surgery. Even when the women lost to follow-up were included in the analysis as treatment failures, the overall success rate for both procedures was >80%. Only two reports randomly comparing retropubic and transobturator midurethral sling procedures, with a follow-up period of 4 yr and 5 yr, respectively [18,19], could be found. Both reports including smaller numbers of women than the present trial found no difference in cure rate between the procedures. The cure rates were slightly lower than in the present trial, which might be explained by the fact that all the surgeons of our trial were experienced specialists who had undergone the systematic nationwide training and certification needed at the time in Finland [20].

Adverse tissue reactions caused by the tape material were not found at the 5-yr visit. New-onset urgency incontinence was seen in <3% of the women. Interesting was the finding that none of the women having urgency incontinence 5 yr after surgery experienced the problem immediately 2 mo after treatment and that only one women had the problem at the 12-mo follow-up and three at the 36-mo follow-up. Another two women had new-onset urgency symptoms without leakage. Noteworthy is the finding that >80% of the women experiencing urgency symptoms preoperatively were relieved of these symptoms 5 yr later. These findings suggest that the risk of developing urgency symptoms with or without leakage after midurethral tape procedure is very low and that actually, as reported earlier, midurethral tape surgery can cure urgency symptoms, the reasons for which remain uncertain [21,22]. A weakness concerning the relevance of these findings is that urodynamics were not performed in these women, and the diagnosis of urgency incontinence is thus based on the subjective perception of the women themselves as registered through the UDI-6 and the DIS questionnaires.

Because invasive urodynamics were not performed, direct objective signs of voiding difficulties at 5 yr after surgery could not be investigated. Indirect signs of bladder emptying problems could be the occurrence of recurrent UTIs and/or PVR >100 ml. Only 6% of the women had three or more UTIs during the past 2 yr; exclusion criteria were more than three UTIs during the past year. The women with three or more UTIs did not differ from those who had not experienced UTI regarding the amount of PVR. All together 13 women had a PVR >100 ml, 2 of these had had a UTI, 5 reported slight but not bothering voiding difficulties, and 6 were completely satisfied with their situation. It therefore seems as if voiding problems and recurrent UTI 5 yr after surgery with midurethral tapes is a rather minor problem. The yearly incidence of UTI in a normal population of the same age as the women of the present trial has been found to be as high as 10–20% [23]. Thus an incidence of 21% during a 2-yr follow-up of the present trial does not differ from the incidence of a normal population.

5. Conclusions

The long-term follow-up results of the present randomized trial comparing the retropubic TVT procedure with the inside-out TVT-O procedure reveals no difference in cure rate or complication rate between the two operations. Both objective and subjective cure rates were >80% in both groups even when women lost to follow-up were included as failures. The complication rates were low with no difference between groups. No late-onset adverse effects of the used tape material were seen.

Author contributions: Carl Gustaf Nilsson had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Laurikainen, Valpas, Nilsson.
Acquisition of data: Laurikainen, Valpas, Aukee, Kivelä, Rinne, Takala, Nilsson.
Analysis and interpretation of data: Laurikainen, Nilsson.
Drafting of the manuscript: Laurikainen, Nilsson.
Critical revision of the manuscript for important intellectual content: Laurikainen, Valpas, Aukee, Nilsson.
Statistical analysis: None.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Nilsson.
Other (specify): None.

Financial disclosures: Carl Gustaf Nilsson certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Eija Laurikainen is an invited speaker at Pfizer and teaches educational courses at Astellas, Ethicon, and AMS. Antti Valpas is an invited speaker at Ethicon and Astellas. Teuvo Takala is an invited speaker at Astellas and Pfizer. Carl G. Nilsson is an invited speaker at Astellas, Ethicon, and Pfizer and consults for Astellas, Ethicon, and Pfizer.

Funding/Support and role of the sponsor: Finnish government research funding.

References

[1] Hannestad YS, Rortveit G, Sandvik H, et al. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPICONT study. J Clin Epidemiol 2000;52:1150–7.
[2] Minassian VA, Drutz HP, Al-Badr A. Urinary incontinence as a world wide problem. Int J Gyn Obstet 2003;82:327–38.
[3] Petros PE, Ulmsten U. An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl 1990;153:7–31.
[4] Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.
[5] Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 2008;19:1043–7.
[6] Ulmsten U, Johnson P, Rezapour M. A three-year follow-up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br J Obstet Gynecol 1999;106:345–50.
[7] Delorme E. Transobturator urethral suspension: Mini-invasive procedure in treatment of stress urinary incontinence in women. Prog Urol 2001;11:1306–13.
[8] De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol 2003;44:724–30.

[9] Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 2010;362:2066–76.
[10] Rinne K, Laurikainen E, Kivelä A, et al. A randomized trial comparing TVT with TVT-O: 12 month results. Int Urogynecol J 2008;19:1049–54.
[11] Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114:522–31.
[12] Laurikainen E, Valpas A, Kivelä A, et al. Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. Obstet Gynecol 2007;109:4–11.
[13] Palva K, Rinne K, Aukee P, et al. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36 months results. Int Urogynecol J 2010;21:1049–55.
[14] Kauppila A, Alavaikko P, Kujansuu E. Detrusor instability score in the evaluation of stress urinary incontinence. Acta Obstet Gynecol Scand 1982;61:137–41.
[15] Baden WF, Walker TA. Genesis of the vaginal profile: a correlated classification of vaginal relaxation. Clin Obstet Gynecol 1972;15:1048–54.
[16] Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn 1995;14:131–9.
[17] Stach-Lempinen B, Kujansuu E, Laippala P, Metsanoja R. Visual analogue scale, urinary incontinence severity score and 15 d-psychometric testing of three different health-related quality-of-life instruments for urinary incontinent women. Scand J Urol Nephrol 2001;35:476–83.
[18] Ballester M, Bui C, Frobert JL, et al. Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicenter study comparing the retropubic and the transobturator routes. World J Urol 2012;30:117–22.
[19] Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomized trial. Eur Urol 2010;58:671–7.
[20] Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 2002;81:72–7.
[21] Palva K, Nilsson CG. Prevalence of urinary urgency symptoms decreases by mid-urethral sling procedures for treatment of stress incontinence. Int Urogynecol J 2011;22:1241–7.
[22] Abdel-Fattah M, Hopper LR, Mostafa A. Evaluation of transobturator tension-free vaginal tapes in surgical management of mixed urinary incontinence: 3-year outcomes of a randomized controlled trial. J Urol 2014;191:114–9.
[23] Schleupner CJ. Urinary tract infections. Postgrad Med 1997;101:231–7.

INTERNATIONAL UROLOGY
International Journal of Urology (2014) 21, 1167–1170 doi: 10.1111/iju.12544

Original Article: Clinical Investigation

Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation

David J Osborn, Roger R Dmochowski, Catherine J Harris, Jill J Danford, Melissa R Kaufman, Stephen Mock, Laura Chang Kit, Benjamin McCormick and W Stuart Reynolds

Department of Urology, Vanderbilt University Medical Center, Nashville, Tennessee, USA

Abbreviations & Acronyms
BMI = body mass index
IQR = interquartile range
UTI = urinary tract infection

Correspondence: David James Osborn M.D., Department of Urology, Vanderbilt University Medical Center, A1302 Medical Center North, Nashville, TN 37232-2765, USA. Email: david.osborn@vanderbilt.edu

Received 31 January 2014; accepted 27 May 2014.
Online publication 14 July 2014

Objectives: To evaluate the technical and patient characteristics associated with the development of mesh perforation and exposure in patients after midurethral sling surgeries.

Methods: After a retrospective review of referred patients, the risk of mesh perforation of the urinary tract over exposure in the vagina was analyzed with multivariate logistic regression, adjusting for the possible predictors of age, body mass index, smoking status at the time of mesh placement, presence of diabetes, type of sling placed, type of surgeon and trocar injury at the time of mesh placement.

Results: A total of 77 women were identified, 27 with mesh perforation and 50 with mesh exposure. The patients' average body mass index was 29.2, and 13% were diabetic. Nine (33%) patients in the perforation group and two (4%) patients in the exposure group had evidence of trocar injury to the bladder or urethra at the time of mesh placement ($P < 0.001$). After multivariate logistic regression analysis, trocar injury (odds ratio 25.90, 95% confidence interval 2.84–236.58, $P = 0.004$) and diabetes (odds ratio 9.90, 95% confidence interval 1.1.25–78.64, $P = 0.03$) were associated with an increased risk of mesh perforation. Increased body mass index (odds ratio 0.88, 95% confidence interval 0.77–0.99, $P = 0.05$) was associated with a decreased risk of mesh perforation. Finally, postoperative hematomas and blood transfusions occurred more commonly in the mesh perforation group (15% *vs* 0%, $P = 0.01$).

Conclusions: Trocar injury, diabetes and bleeding complications at the time of surgery are associated with higher risk of mesh perforation in patients undergoing midurethral sling placement.

Key words: complication, erosion, extrusion, incontinence, trocar.

Introduction

Before 1998, the most common surgeries for stress urinary incontinence were retropubic urethropexies, needle suspensions, autologous pubovaginal slings and collagen injections.[1] In 1998, the Food and Drug Administration approved the first midurethral sling for stress urinary incontinence. Over the next 10 years, the utilization of the midurethral sling increased dramatically, and multiple studies have shown its benefit over traditional surgeries for stress urinary incontinence not utilizing mesh.[2,3] However, as the utilization of synthetic mesh increased, complications related to its implantation started to become apparent.[4]

The most common complications of mesh surgery are mesh exposure and dyspareunia, and the most serious complications are perforation of organs, such as the bladder, urethra and bowel. In 2010, the International Continence Society and International Urogynecological Association released a report intended to clarify and standardize the terminology related to complications from insertion of synthetic and biological materials during female pelvic floor surgery.[5] According to that report, synthetic mesh is termed a prosthesis and a biological implant is termed a graft. Mesh located in the bladder or urethra is termed a perforation and extrusion of mesh through the vagina or skin is termed exposure.

Ranging from 0 to 8.1% in the literature, mesh exposure rates are variable with midurethral slings.[6,7] In addition, the rate of bladder or urethral injury with a trocar at the time of surgery is also variable and ranges from 2.7 to 23.8%.[8,9] Though few studies comment on mesh perforation into the bladder or urethra, the incidence in the literature falls between 0 and 0.6%.[3,10,11] The purpose of the present study was to evaluate technical and patient characteristics associated with mesh perforation and mesh exposure after midurethral sling surgeries that utilize a trocar and synthetic mesh.

Table 1 Demographic and clinical characteristics of patients with mesh perforation and mesh exposure

Variables	Mesh perforation (n = 27)	Mesh exposure (n = 50)	P-value
Age	50.1 ± 12.1	49.0 ± 11 5	0.68
BMI	28.0 ± 5.2	29.9 ± 6.0	0.18
Smoker	7 (26)	16 (32)	0.31
Diabetes	5 (19)	3 (6)	0.09
Prior hysterectomy	23 (85)	43 (86)	0.92
Concomitant pelvic surgery	10 (37)	27 (54)	0.15
Previous Incontinence surgery	5 (18)	3 (6)	0.09
Cystoscopy performed	22 (81)	42 (84)	0.78
Trocar injury	9 (33)	2 (4)	<0.001
Postoperative hematoma or transfusion	4 (15)	0	0.01
Type of surgeon			
Gynecologist	13 (48)	27 (74)	0.03
Urologist	14 (52)	13 (26)	0.03
Direction of trocar passage			
Retropubic	20 (74)	27 (54)	0.09
Transobturator	7 (26)	23 (46)	0.09
Median (IQR) months presentation	22 (47)	6 (16.2)	0.01
Urinary presenting primary symptom	19 (70)	2 (4)	<0.001

Mean ± SD, n (%). Months presentation, months from mesh placement to discovery of complication.

Methods

The Vanderbilt Institutional Review Board (IRB# 121734) approved the present retrospective study. The electronic medical records of all female patients referred to the urology and urogynecology services at Vanderbilt University Medical Center for mesh exposure and mesh perforation from January 2003 to January 2012 were reviewed. Patients were identified using Common Procedural Terminology (CPT) codes for endoscopic foreign body removal, urethrolysis, sling revision or removal, female urethroplasty, cystorraphy and simple or partial cystectomy. Any patient whose source procedure operative report was not available was excluded. The operative reports were examined for the following study variables: age, implanting surgeon (urologist or gynecologist), source procedure and perioperative complications. Symptoms and time to recognition and repair were also studied.

Statistical analysis

Discrete variables are reported as frequency and proportions as percentages. Continuous variables are reported as median and mean values. Initial statistical analysis of continuous variables, such as age, was carried out using the t-test mean comparison test, and analysis of categorical variables was carried out using Pearson's χ^2-test or Fisher's exact test. The eligible cohort of patients was separated into two groups: patients who had mesh exposure in the vagina and patients who had mesh perforation into the bladder or urethra. The associations between mesh perforation and age, BMI, smoking status, diabetes, type of surgeon, location of trocar passage, and perioperative complications including trocar injury were assessed with multivariate logistic regression.

Results

Overall, 123 patients were referred for mesh exposure ($n = 80$) and perforation ($n = 43$) related to midurethral sling surgery over the 10-year study period. Source operative reports were available for 77 patients (67%), who were included in this analysis. Of the 77 women, 27 had mesh perforation and 50 had vaginal mesh exposure. In the mesh perforation group, 15 women had mesh perforation of the urethra and 12 women had mesh perforation of the bladder. The average age was 49.4 years (range 26–81 years). The median time between mesh placement and presentation was 9.5 months (IQR 32). Table 1 shows the results of a comparison of demographic and clinical variables between the two study groups.

Trocar injury was defined as a trocar that had to be removed and replaced at the time of mesh placement because it was found to be in or too close to the bladder or urethral lumen during cystoscopy. In total, there were 11 documented trocar injuries. Only one of these 11 patients underwent transobturator midurethral sling placement.

Overall, four patients (all in the perforation group) developed a bleeding complication in the immediate postoperative period. There were two pelvic hematomas, one vaginal hematoma and one blood transfusion. Only one patient with a documented trocar injury at the time of surgery developed a bleeding complication.

Overall, 83% (64) of patients had a documented cystoscopy after passage of the midurethral sling trocar and 17% (13) of the study population did not. A total of 12 patients with no documented cystoscopy underwent a transobturator sling and one underwent a retropubic sling. Patients were defined as having a prior hysterectomy if they had a history of hysterectomy on a previous day. Patients were defined as having concomitant pelvic surgery if they underwent prolapse repair or a hysterectomy at the same time as their sling surgery.

The presenting symptom was the primary complaint of the patient at the time when their mesh perforation or exposure was first diagnosed. Table 2 shows the results of the different presenting symptoms in the two groups of patients. In the perforation group, five of the seven patients with incontinence had a

Table 2 Comparison of primary presenting symptom between two groups

Presenting symptom, *n* (%)	Mesh perforation (*n* = 27)	Mesh exposure (*n* = 50)	*P*-value
Dyspareunia	2 (7)	18 (36)	0.01
Vaginal bleeding	0	10 (20)	0.01
Vaginal pain	4 (15)	10 (20)	0.57
Felt on exam	0	4 (8)	0.13
Partner sexual discomfort	0	3 (6)	0.19
Vaginal discharge	0	3 (6)	0.19
Incontinence	7 (26)	1 (2)	0.001
Recurrent UTI	2 (7)	0	0.05
Hematuria	1 (4)	0	0.17
Irritative voiding symptoms	11 (41)	1 (2)	<0.001

Table 3 Multivariate analysis of independent variables for mesh perforation

Variable	Odds ratio	95% confidence interval	*P*-value
Age	1.00	0.95–1.06	0.86
BMI	0.88	0.77–0.99	0.05
Concomitant pelvic surgery	0.43	0.11–1.62	0.21
Diabetes	9.90	1.25–78.64	0.03
Previous incontinence surgery	4.19	0.59–29.65	0.15
Retropubic trocar passage	0.92	0.24–3.50	0.90
Smoker	0.73	0.18–2.88	0.65
Trocar injury	25.90	2.84–236.58	0.004
Type of surgeon	1.40	0.40–4.94	0.60

concomitant vesicovaginal fistula. In 16 (59%) patients, mesh perforation was discovered on the first postoperative cystoscopy, and in eight (30%) patients perforation was discovered on the second cystoscopy.

After adjusting for covariates, an increased risk of mesh perforation was associated with trocar injury (OR 25.90, 95% CI 2.84–236.58) and diabetes (OR 9.90, 95% CI 1.1.25–78.64). Increased BMI appeared protective, with a decreased risk of mesh perforation (OR 0.88, 95% CI 0.77–0.99). Age, smoking status, the type of performing surgeon, previous incontinence surgery, concomitant pelvic surgery and transobturator versus retropubic trocar placement were not found to be significant risk factors for mesh perforation. Table 3 shows the results of a multivariate analysis of independent variables for mesh perforation.

Discussion

The present study sought to examine mesh complications after midurethral sling surgery by comparing two groups of patients that are commonly referred for tertiary surgical consultation. Because mesh perforation of the lower urinary tract is such a rare complication, it is difficult to examine this issue in a prospective manner. With an incidence rate of 0.6%, there is only one randomized prospective study in the literature that comments on mesh perforation into the bladder or urethra as an adverse event after midurethral sling surgery.[3] Interestingly, this 0.6% incidence is consistent with the rate of mesh urinary tract perforation in two retrospective studies of over 1000 patients who underwent midurethral sling surgery.[11,12]

In 2007, Chen *et al.* carried out a retrospective study of 247 patients who underwent consecutive midurethral sling surgeries, and found that diabetes mellitus was a significant risk factor for vaginal exposure.[13] In the study herein described, diabetes mellitus was associated with an increased risk of mesh perforation into the bladder. Poor wound healing is a known problem related to diabetes mellitus after pelvic surgery.[14] It is possible that diabetes affects the normal incorporation of mesh into the tissue of the pelvis.

In 2010, Stav *et al.* presented their results of a retrospective study of 1136 patients who underwent midurethral sling surgery examining risk factors related to trocar injury at the time of sling placement. That study found that among other factors, a low BMI (<30 kg/mg^2) was associated with an increased risk of trocar injury. Similarly, the present study found a significant relationship between lower BMI and an increased risk of mesh perforation into the bladder or urethra. This might also have to do with the possibility that increased adipose tissue displaces the bladder away from the pubic bone. Surgeons should therefore make extra effort to stay in contact with the posterior bony surface during trocar passage in thin patients.

Previous studies have shown an association between concomitant pelvic surgery at the time of midurethral sling placement and complications.[15] In the present study, we found no association between concomitant pelvic surgery and mesh perforation compared with exposure. In addition, previous studies have shown an increased incidence of bladder trocar injury in patients with previous incontinence surgery.[16,17] Although the rate of previous incontinence surgery in the study herein described was higher in the mesh perforation group, this did not reach statistical significance.

In an attempt to examine if surgical training or experience was associated with a lower rate of mesh perforation, surgeon type was analyzed. Although univariate analysis showed that the rate of mesh perforation was higher with urologists, this significance was not maintained with multivariate analysis.

The established methods to prevent trocar bladder injury during midurethral sling surgery are to ensure that the bladder is drained before trocar passage and to keep the trocar in contact with the inferior surface of the pubic symphysis or ischiopubic rami during trocar passage. In addition, cystoscopy should always be carried out with a 70-degree lens in a completely filled bladder so that a fold of mucosa does not obscure a trocar injury.

Trocar injury to the bladder at the time of midurethral sling surgery is traditionally thought of as a benign complication; however, in the present study we found that it could be a risk factor for eventual mesh perforation. The limitations of the present small retrospective study make it impossible to conclusively state that there is a direct causal link between trocar injuries and mesh perforation. Clearly there are many potential confounding variables, such a surgeon experience, and other unknown patient factors that might have contributed to this result. Further research in this area is required, but will most likely be limited by the uncommon nature of this complication.

In the present study, the time from mesh placement to diagnosis was delayed significantly more in the mesh perforation

group when compared with the exposure group (22 *vs* 6 months). This highlights the need for physicians to maintain a high level of suspicion for mesh perforation in patients with hematuria or other lower urinary tract symptoms after midurethral sling surgery. Interestingly, even if a provider does suspect mesh perforation, the first cystoscopy after surgery only revealed mesh 59% of the time.

In our 10-year study from 2003 to 2012, 83% of surgeons documented an intraoperative cystoscopy. In the early 2000s, there was still considerable debate among pelvic surgeons as to whether intraoperative cystoscopy was necessary after midurethral sling surgery or anterior prolapse repairs.[18] In fact, initial marketing of the transobturator and single-incision midurethral slings advertised the lack of need for intraoperative cystoscopy as an advantage over retropubic midurethral slings.[19] Intraoperative cystoscopy is recommended by the authors of the present article during sling and prolapse surgeries to increase identification of intraoperative urinary tract injuries, which would otherwise be missed.[20,21]

Patients with mesh perforation were also more likely to have a perioperative hematoma or require a blood transfusion after midurethral sling surgery. It is possible that bleeding complications are independent risk factors that contribute to mesh perforation. However, it is more likely that bleeding and mesh perforation of the urinary tract complications are the result of a mixture of patient and surgical factors.

In conclusion, mesh perforation into the urinary tract is an increasingly referred complication to tertiary care referral centers. Patients often have a delay in diagnosis and subsequent management when compared with mesh exposure patients. Our analysis suggests the risk for mesh perforation after midurethral slings is increased in patients with diabetes and trocar injury at the time of the procedure, and is inversely related to BMI. Although trocar injury at the time of midurethral sling surgery is traditionally thought of as a benign complication with no increased risk of an adverse outcome, the present study shows that this might not be the case. Because of the low incidence of mesh perforation, the results of the present study do not change the fact that if a trocar injury occurs during midurethral sling surgery, the surgeon should replace the trocar until it is outside the urinary tract and continue with the procedure.

Conflict of interest

None declared.

References

1 Jonsson Funk M, Levin PJ, Wu JM. Trends in the surgical management of stress urinary incontinence. *Obstet. Gynecol.* 2012; **119**: 845–51.

2 Jonsson Funk M, Siddiqui NY, Kawasaki A, Wu JM. Long-term outcomes after stress urinary incontinence surgery. *Obstet. Gynecol.* 2012; **120**: 83–90.

3 Ward KL, Hilton PUK, Ireland TVT Trial Group. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. *BJOG* 2008; **115**: 226–33.

4 Novara G, Galfano A, Boscolo-Berto R *et al.* Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. *Eur. Urol.* 2008; **53**: 288–308.

5 Haylen BT, Freeman RM, Lee J *et al.* An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related to native tissue female pelvic floor surgery. *Int. Urogynecol. J.* 2012; **23**: 515–26.

6 Zullo MA, Plotti F, Calcagno M *et al.* One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. *Eur. Urol.* 2007; **51**: 1376–82; discussion 1383–4.

7 Tseng L-H, Wang AC, Lin Y-H, Li SJ, Ko YJ. Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2005; **16**: 230–5.

8 Andonian S, Chen T, St-Denis B, Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. *Eur. Urol.* 2005; **47**: 537–41.

9 Porena M, Costantini E, Frea B *et al.* Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. *Eur. Urol.* 2007; **52**: 1481–90.

10 Richter HE, Albo ME, Zyczynski HM *et al.* Retropubic versus transobturator midurethral slings for stress incontinence. *N. Engl. J. Med.* 2010; **362**: 2066–76.

11 Hammad FT, Kennedy-Smith A, Robinson RG. Erosions and urinary retention following polypropylene synthetic sling: Australasian survey. *Eur. Urol.* 2005; **47**: 641–6; discussion 646–7.

12 Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet. Gynecol. Scand.* 2002; **81**: 72–7.

13 Chen H-Y, Yeh L-S, Chang W-C, Ho M. Analysis of risk factors associated with surgical failure of inside-out transobturator vaginal tape for treating urodynamic stress incontinence. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2007; **18**: 443–7.

14 Christian CK, Kwaan MR, Betensky RA, Breen EM, Zinner MJ, Bleday R. Risk factors for perineal wound complications following abdominoperineal resection. *Dis. Colon Rectum* 2005; **48**: 43–8.

15 Anger JT, Litwin MS, Wang Q, Pashos CL, Rodriguez LV. The effect of concomitant prolapse repair on sling outcomes. *J. Urol.* 2008; **180**: 1003–6.

16 Lo T-S, Horng S-G, Chang C-L, Huang H-J, Tseng L-H, Lian C-C. Tension-free vaginal tape procedure after previous failure in incontinence surgery. *Urology* 2002; **60**: 57–61.

17 Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with recurrent stress urinary incontinence-a long-term follow up. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2001; **12** (Suppl 2): S9–11.

18 Kwon CH, Goldberg RP, Koduri S, Sand PK. The use of intraoperative cystoscopy in major vaginal and urogynecologic surgeries. *Am. J. Obstet. Gynecol.* 2002; **187**: 1466–71; discussion 1471–2.

19 Farrell S, Chan M, Schulz J. Midurethral minimally invasive sling procedures for stress urinary incontinence. *J. Obstet. Gynaecol. Can.* 2008; **30**: 728–33.

20 Appell RA, Dmochowski R, Blaivas JG. Guideline for the surgical management of female stress urinary incontinence: 2009 Update.

21 ACOG Committee Opinion. Number 372. July 2007. The role of cystourethroscopy in the generalist obstetrician-gynecologist practice. *Obstet. Gynecol.* 2007; **110**: 221–4.

EUROPEAN UROLOGY 58 (2010) 218–238

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Platinum Priority – Female Urology – Incontinence

Editorial by Firouz Daneshgari on pp. 239–241 of this issue

Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence

Giacomo Novara[a,*], *Walter Artibani*[b], *Matthew D. Barber*[c], *Christopher R. Chapple*[d], *Elisabetta Costantini*[e], *Vincenzo Ficarra*[a], *Paul Hilton*[f], *Carl G. Nilsson*[g], *David Waltregny*[h]

[a] *Department of Oncological and Surgical Sciences, Urology Clinic, University of Padua, Padua, Italy*
[b] *Department of Biomedical and Surgical Sciences, Urology Clinic, University of Verona, Verona, Italy*
[c] *Obstetrics, Gynecology, and Women's Health Institute, Cleveland Clinic, Cleveland, Ohio, USA*
[d] *Sheffield Teaching Hospitals NHS Foundation Trust, Department of Urology, The Royal Hallamshire Hospital, Sheffield, UK*
[e] *Section of Urology and Andrology, Department of Medical-Surgical Specialties and Public Health, University of Perugia, Perugia, Italy*
[f] *Directorate of Women's Services, Royal Victoria Infirmary, Newcastle upon Tyne, UK*
[g] *Department of Obstetrics and Gynecology, Helsinki University Central Hospital, Helsinki, Finland*
[h] *Department of Urology, University of Liège, Liège, Belgium*

Article info

Article history:
Accepted April 13, 2010
Published online ahead of print on April 23, 2010

Keywords:
Stress urinary incontinence
Burch colposuspension
Pubovaginal sling
Stress urinary incontinence
Retropubic vaginal tape
Tension-free tape
Transobturator tape

Abstract

Context: Burch colposuspension, pubovaginal sling, and midurethral retropubic tape (RT) and transobturator tape (TOT) have been the most popular surgical treatments for female stress urinary incontinence (SUI). Several randomized controlled trials (RCTs) have been published comparing the different techniques, with conflicting results.

Objective: Our aim was to evaluate the efficacy, complication, and reoperation rates of midurethral tapes compared with other surgical treatments for female SUI.

Evidence acquisition: A systematic review of the literature was performed using the Medline, Embase, Scopus, Web of Science databases, and Cochrane Database of Systematic Reviews.

Evidence synthesis: Thirty-nine RCTs were identified. Patients receiving midurethral tapes had significantly higher overall (odds ratio [OR]: 0.61; confidence interval [CI]: 0.46–0.82; $p = 0.00009$) and objective (OR: 0.38; CI: 0.25–0.57; $p < 0.0001$) cure rates than those receiving Burch colposuspension, although they had a higher risk of bladder perforations (OR: 4.94; CI: 2.09–11.68; $p = 0.00003$). Patients undergoing midurethral tapes and pubovaginal slings had similar cure rates, although the latter were slightly more likely to experience storage lower urinary tract symptoms (LUTS) (OR: 0.31; CI: 0.10–0.94; $p = 0.04$) and had a higher reoperation rate (OR: 0.31; CI: 0.12–0.82; $p = 0.02$). Patients treated with RT had

* Corresponding author. Department of Oncological and Surgical Sciences, Urology Clinic, University of Padua, Padua, Italy; Monoblocco Ospedaliero, IV Floor, Via Giustiniani 2, 35128, Padua, Italy. Tel. +39 049 8212720; Fax: +39 049 8218757.
E-mail address: giacomonovara@gmail.com (G. Novara).

0302-2838/$ – see back matter doi:10.1016/j.eururo.2010.04.022

slightly higher objective cure rates (OR: 0.8;CI: 0.65–0.99; $p = 0.04$) than those treated with TOT; however, subjective cure rates were similar, and patients treated with TOT had a much lower risk of bladder and vaginal perforations (OR: 2.5; CI: 1.75–3.57; $p < 0.00001$), hematoma (OR: 2.62; CI: 1.35–5.08; $p = 0.005$), and storage LUTS (OR: 1.35; CI: 1.05–1.72; $p = 0.02$). Meta-analysis demonstrated similar outcomes for TVT-O (University of Liège, Liège, Wallonia, Belgium) and Monarc (AMS, Minnetonka, MN, USA).

Conclusions: Patients treated with RT experienced slightly higher continence rates than those treated with Burch colposuspension, but they faced a much higher risk of intraoperative complications. RT and pubovaginal slings were similarly effective, although patients with pubovaginal slings were more likely to experience storage LUTS. The use of RT was followed by objective cure rates slightly higher than TOT, but subjective cure rates were similar. TOT had a lower risk of bladder and vaginal perforations and storage LUTS than RT. The strength of these findings is limited by the heterogeneity of the outcome measures and the short length of follow-up.

1. Introduction

Female stress urinary incontinence (SUI) is a common condition, with prevalence rates ranging from 12.8% to 46.0% [1]. Although several methodological issues can influence the epidemiological figures, there is no question that female SUI has an significant negative impact on quality of life and, in particular, on the social, physical, psychological, occupational, and sexual aspects of life [2]. Moreover, management of SUI puts an enormous burden on the health care system, estimated to be as high as $19.5 billion annually in the United States [3] and £740 million annually in the United Kingdom [4].

Surgical treatment is the standard approach for women with SUI who have failed conservative management strategies such as lifestyle changes, physical therapies, scheduled voiding regimes, and behavioral therapies [5]. Although hundreds of different surgical procedures have been reported, the ideal surgical technique—that is, a procedure that is simple, inexpensive, easy to learn and perform, minimally invasive, with high and durable efficacy, and without long-term morbidity and functional sequelae—does not yet exist [6].

Both Burch colposuspension and pubovaginal slings are time-honored procedures, with solid evidence of their efficacy at long-term follow-up. Specifically, both procedures have been reported to be followed by 10-yr success rates in the range of 55–70% [7]. However, neither of the techniques is minimally invasive, and both are followed by significant risks of de novo storage symptoms (8–27% following colposuspension and 3–23% following pubovaginal sling), voiding dysfunction (2–27% following colposuspension and up to 11% with 1.5–7.8% long-term self-catheterization following pubovaginal sling), and pelvic organ prolapse (2.5–27% following colposuspension) [7].

Since the first reports from the Ulmsten group [8], the application of tension-free vaginal tape (TVT), the first polypropylene midurethral tape put on the market, has become one of the most commonly performed procedures worldwide, largely because of the ease of performing the procedure and its short-term high success rates. In 2008, Nilsson et al reported outcomes 11 yr after the operation, demonstrating that 90% of the women treated were still objectively cured at the last follow-up without any significant late-onset adverse effects [9].

Since the advent of TVT, other retropubic tapes (RT) and, more recently, transobturator tapes (TOT) have been introduced, making midurethral sling procedures both less invasive and safer [10].

Based on a systematic literature search performed in January 2007, Novara et al reported two systematic reviews and meta-analyses of randomized controlled trials (RCTs) evaluating the efficacy and complication rates of TVT compared with Burch colposuspension, pubovaginal slings, and other midurethral tapes [11,12]. On the whole, the data from the two meta-analyses suggested that TVT was significantly more effective than colposuspension and was followed by similar complication rates; the data also showed that TVT was similar in efficacy to pubovaginal slings, which are followed by significantly higher perioperative morbidity. Finally, the two meta-analyses demonstrated that TVT and TOT had similar efficacy, although the risk of bladder perforations, pelvic hematoma, and storage lower urinary tract symptoms (LUTS) was significantly less common in patients treated with TOT [11,12].

The strength of the recommendations derived from these two meta-analyses was limited by the short median follow-up and poor methodological quality of several of the RCTs included. Since then, several other RCTs have been published, mainly comparing RT with TOT and featuring longer follow-up extensions than some of the other previously available studies [13,14]. Consequently, based on the recommendation of the Cochrane Collaboration to update systematic reviews at least every 2 yr [15], we elected to update our previous meta-analyses of the literature in the field of midurethral slings for the treatment of primary female SUI.

2. Evidence acquisition

2.1. Materials and methods

The updated systematic review of the literature was performed in August 2009 using the Medline, Scopus, Web of Science, and Embase databases. The Medline search used a complex search strategy including both medical subject heading (MeSH) and free-text protocols, as was done in the previous review [11,12]. Specifically, the MeSH search was conducted by combining the following terms retrieved from the MeSH browser provided by Medline: *Urinary Incontinence, Stress,* and *Suburethral Slings.* Multiple free-text searches were also performed, searching for the following terms individually in the fields title and abstract of the records: *Urinar*incont*, TVT, tension-free vaginal tape*, Tension-free vaginal sling*, Transobturator tape*, Transobturator sling*, TVT-obturator, TVT-O, TOT, suprapubic arc sling*, SPARC sling*, intravaginal slingplasty, IVS sling, Uratape, ObTAPE, Prepubic sling*, Prepubic TVT, Prepubic tape*, PelviLace, Ureter, Aris, In-Fast, Monarc, I-Stop,* and *BioArc.* Subsequently, the search results were pooled, and the following limits used: humans, Entrez date from January 1, 2007. No limitations regarding language of publication or type of publication were used. The searches on Embase, Scopus, and Web of Science used only the free-text protocol, with the same keywords. Subsequently, the query results were pooled and the same temporal limit applied. Moreover, Cochrane Database of Systematic Reviews was searched using the keyword *urinary incontinence.* A manual search of congress abstracts was not performed.

A total of 327 records were retrieved from Medline, 601 from Scopus, 502 from Embase, and 405 from Web of Science. Three of the authors reviewed the full texts to select the papers relevant to the review topic. Discrepancies were solved by open discussion. Specifically, all the RCTs discussing outcomes (ie, continence rates, satisfaction rates, complication rates) from the use of midurethral slings were selected. A single Cochrane review of the pertinent topic was identified [16]. The reference list was searched, identifying 14 further trials.

The selected papers were categorized according to the grade of evidence: An adequately sampled single RCT was considered to have level 1b evidence, a low-quality RCT to have level 2b evidence [17].

The quality of the retrieved RCTs was assessed using the Jadad score [18]. A numerical score between 0 and 5 was assigned as a rough measure of study design and reporting quality, with 0 the weakest and 5 the strongest. One point was assigned if the trial was either randomized or double blinded, and one point was given if an accurate description of dropout patients was provided. Further points were given if randomization and blinding procedures were appropriate; points were subtracted if randomization and blinding procedures were inappropriate or inadequately described. An overall score ≥ 3 indicated a high-quality study [18].

To evaluate the efficacy of the different procedures, both objective criteria (stress test, pad test) and subjective

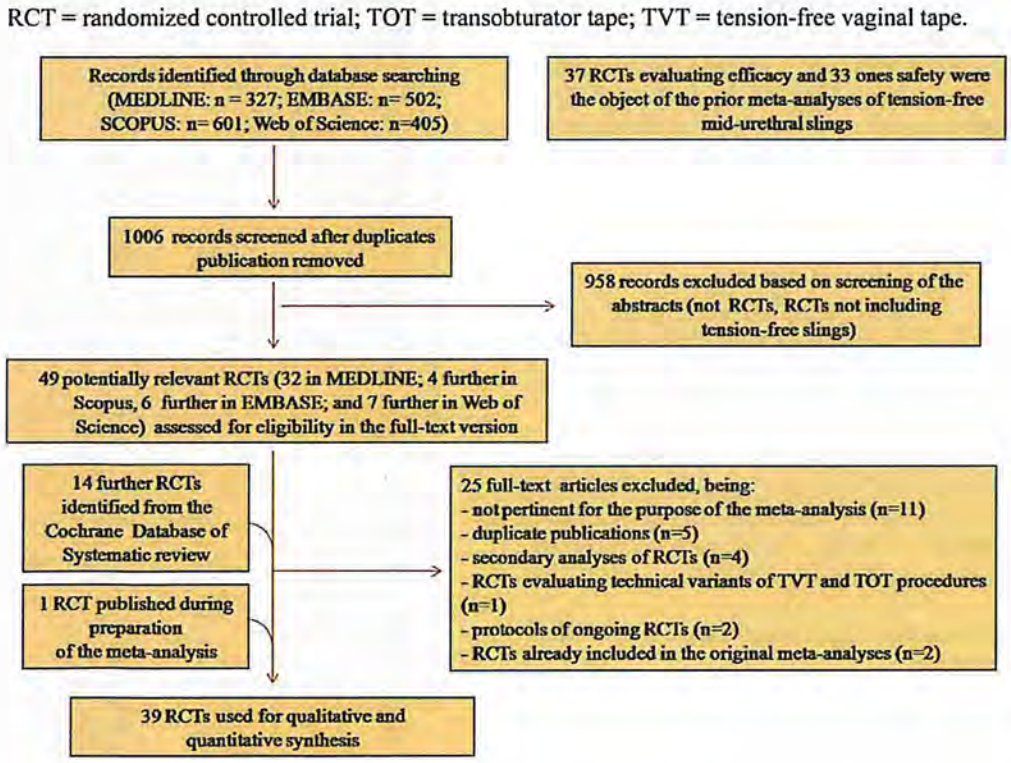


Fig. 1 – Flow diagram of the systematic review and meta-analysis.
RCT = randomized controlled trial; TOT = transobturator tape; TVT = tension-free vaginal tape.

criteria (patients' perception of the clinical improvement, expressed by validated questionnaires, institutional questionnaires, or open interview) were considered, reporting objective and subjective continence rates. In the case of papers reporting patient outcomes through the use of mixed subjective and objective end points (eg, no referred leakage and negative stress test, no referred leakage and negative pad test), an overall continence rate was shown.

Meta-analysis was conducted using Review Manager software v.4.2 (Cochrane Collaboration, Oxford, UK). Specifically, statistical heterogeneity was tested using the χ^2 test. A value of $p < 0.10$ was used to indicate heterogeneity. In the case of a lack of heterogeneity, fixed-effects models were used for the meta-analyses. The results were expressed as weighted means difference and standard deviations for continuous outcomes and as an odds ratio (OR) with a 95% confidence interval (CI) for dichotomous variables. In the comparisons of RT and TOT, the large number of publications with appropriate data allowed us to perform subgroup analysis according to the device used. For all the comparisons, sensitivity analyses limited to RCTs of good methodological quality (ie, those with a Jadad score ≥3) were performed. The presence of publication bias was evaluated through a funnel plot, as previously reported [19]. Briefly, a funnel plot is a scatter plot of the treatment effect estimated by individual studies versus a measure of study size or precision. In this graphic representation, larger and more precise studies are plotted at the top, near the combined effect size, and smaller and less precise studies show a wider distribution below. If there were no publication bias, the studies would be expected to be symmetrically distributed on both sides of the combined effect size line. In the case of publication bias, the funnel plot may be asymmetric because the absence of studies would distort the distribution on the scatter plot.

The study complied with the recently reported Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [20].

3. Evidence summary

Fig. 1 summarizes the literature review process that led to the identification of the 39 RCTs used to update the meta-analysis. Specifically, 7 RCT compared TVT [21–27] and a single TOT [28] with Burch colposuspension; 4 compared RT [29–32] and 1 TOT [33] with autologous pubovaginal slings; 23 compared RT with TOT [34–56], and finally, 3 RCTs compared different TOT [57–59]. Among these publications, there were 14 congress abstracts [21–25,29,31,33,34,36, 38,46, 54,57]. Twelve of the 25 studies were high-quality RCTs [27,28,38,39,40,42,44,48,49,51,53,58].

3.1. *Randomized controlled trials comparing midurethral tapes to Burch colposuspension*

Sivasioglu et al compared the efficacy of Safyre-t TOT (Promedon, Cordoba, Argentina) and Burch colposuspension at 12-mo follow-up, demonstrating fairly similar cure and complication rates results for the two procedures [28].

Table 1 – Comparisons after midurethral tapes and Burch colposuspension: Meta-analysis of all of the randomized controlled trials (RCTs) and sensitivity analyses for high-quality RCTs

Midurethral tapes vs colposuspension	All RCTs						High-quality RCTs					
	RCT	Participants	OR	95% CI of OR	p value	Difference in favor of	RCT	Participants	OR	95% CI of OR	p value	Difference in favor of
Continence rate												
Any definition of continence	11	1195	0.61	0.46–0.82	0.0009	Midurethral tape	4	628	0.48	0.34–0.69	<0.0001	Midurethral tape
Negative stress test	3	528	0.38	0.25–0.57	<0.0001	Midurethral tape	3	528	0.38	0.25–0.57	<0.0001	Midurethral tape
Negative pad test	3	310	0.86	0.49–1.51	0.61	None	2	242	0.87	0.49–1.59	0.65	None
Subjective continence rate	4	400	0.79	0.52–1.21	0.27	None	2	277	0.80	0.48–1.36	0.41	None
Adverse events												
	RCT	Participants	OR	95% CI of OR	p value	Difference in favor of	RCT	Participants	OR	95% CI of OR	p value	Difference in favor of
Bladder perforation	6	865	4.94	2.09–11.68	0.00003	Colposuspension	3	516	5.59	2–15.63	0.001	Colposuspension
Hematoma	4	533	1.16	0.37–3.66	0.80	None	2	416	3.67	0.59–22.7	0.16	None
Urinary tract infection	7	923	1.00	0.53–1.89	0.99	None	3	572	1.92	0.69–5.32	0.21	None
Storage LUTS	10	1128	1.08	0.77–1.52	0.66	None	3	572	1.29	0.84–1.97	0.24	None
Voiding LUTS	11	1081	0.85	0.57–1.25	0.41	None	4	628	0.70	0.45–1.1	0.12	None
Reoperation rate	4	490	0.76	0.40–1.44	0.41	None	2	407	0.74	0.38–1.45	0.38	None

CI = confidence interval; LUTS = lower urinary tract symptoms; OR = odds ratio.

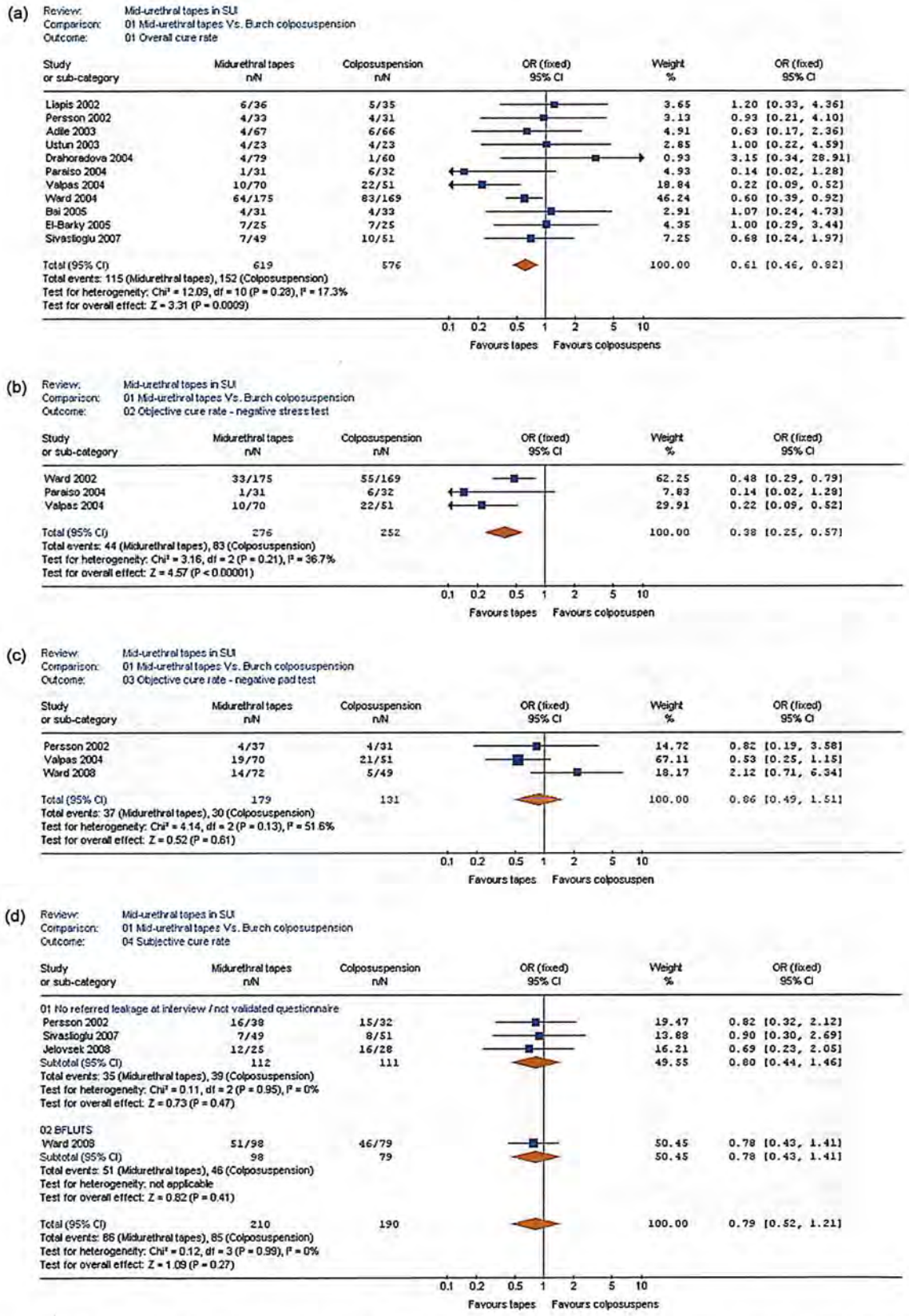
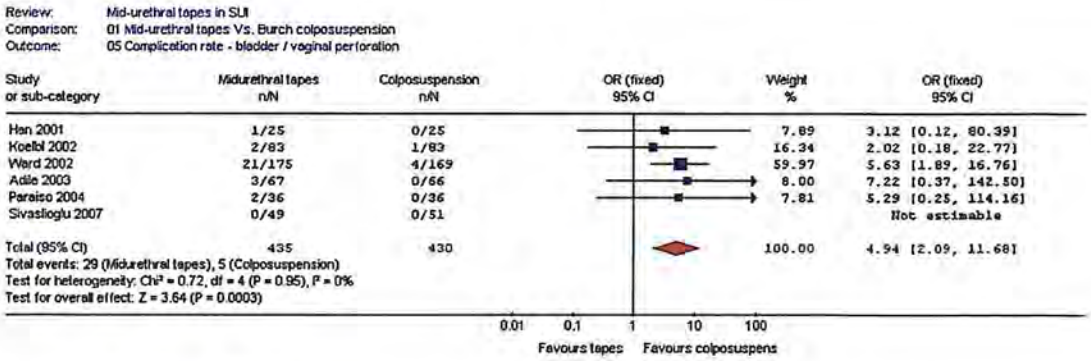
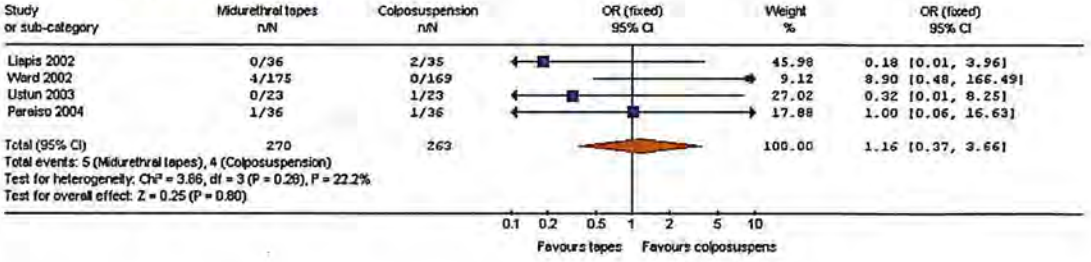


Fig. 2 – Forest plots of comparisons after midurethral tapes and Burch colposuspension. (a) Overall cure rate: continence rate according to any definition of cure; (b) continence rate according to the presence of a negative stress test; (c) continence rate according to the presence of a negative 2-h pad test; (d) subjective continence rate; (e) bladder and vaginal perforation; (f) pelvic hematoma; (g) urinary tract infection; (h) storage lower tract urinary symptoms (LUTS); (i) voiding LUTS; (j) reoperation rate.
CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

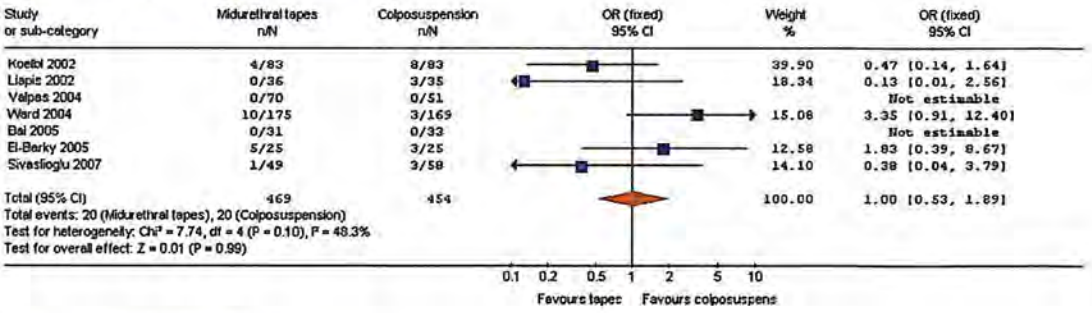
(e)



(f)



(g)



(h)

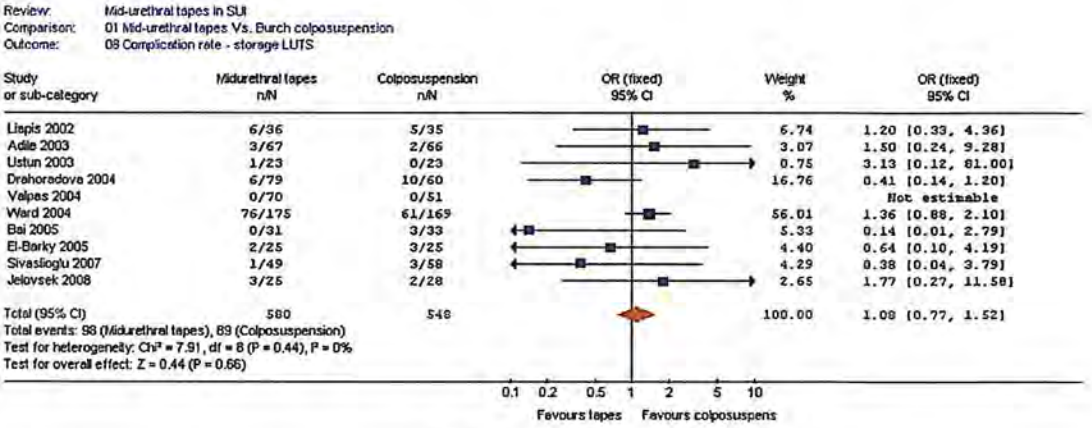


Fig. 2. (Continued)

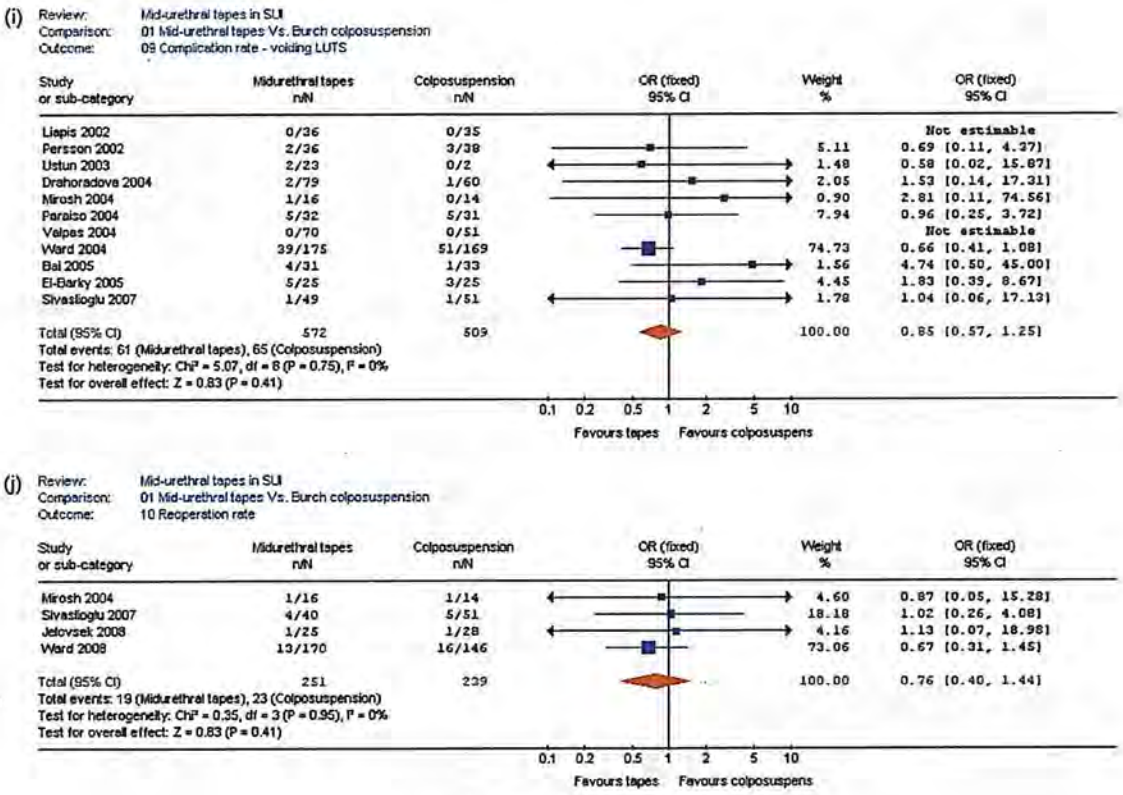


Fig. 2. (Continued).

Jelovsek et al evaluated the classical TVT in comparison with laparoscopic colposuspension at a median follow-up of 64.8 mo, reporting overlapping cure and complication rates [26]. The paper is an update of a study previously reported by Paraiso et al. [14] featuring a longer follow-up. The study from Ward et al. [27] updates at 5-yr follow-up the data from the United Kingdom and Ireland TVT Trial, a highly relevant study that previously had data available only at 2-yr follow-up [13]. All the other studies were published as congress abstracts [21–25]. Only two of these studies were of good methodological quality [27,28].

Supplemental Table 1 in the appendix summarizes continence, complication, and reoperation rates of the RCTs comparing midurethral tapes to Burch colposuspension as a treatment for primary SUI.

Fig. 2 shows the forest plots concerning the meta-analyses of cure, complication, and reoperation rates.

On the whole, midurethral tapes were followed by significantly higher cure rates than Burch colposuspension, considering success rates evaluated according to any definition of continence (OR: 0.61; 95% CI: 0.46–0.82; $p = 0.00009$; Fig. 2a) and the presence of a negative cough test (OR: 0.38; 95% CI: 0.25–0.57; $p < 0.0001$; Fig. 2b). The two procedures were similarly effective according to the presence of a negative pad test (OR: 0.86; 95% CI OR: 0.49–1.51; $p = 0.61$; Fig. 2c) and subjective continence rates (OR: 0.79; 95% CI OR: 0.52–1.21; $p = 0.27$; Fig. 2d). Sensitivity analyses limited to studies of higher methodological quality reconfirmed these identical findings (Table 1).

With regard to complication rates, bladder perforation was significantly more common after midurethral tapes (OR: 4.94; 95% CI: 2.09–11.68; $p = 0.00003$; Fig. 2e), whereas the risk of pelvic hematoma (OR: 1.16; 95% CI: 0.37–3.66; $p = 0.80$; Fig. 2f), urinary tract infections (OR: 1.35; 95% CI: 0.63–2.90; $p = 0.44$; Fig. 2g), storage LUTS (OR: 1.08; 95% CI: 0.77–1.52; $p = 0.66$; Fig. 2h), voiding LUTS (OR: 0.85; 95% CI: 0.57–1.25; $p = 0.41$; Fig. 2i), and reoperation (OR: 0.76; 95% CI: 0.40–1.44; $p = 0.41$; Fig. 2j) were similar between the two surgical treatments. Sensitivity analyses limited to studies of higher methodological quality reconfirmed these identical findings (Table 1).

3.2. *Randomized controlled trials comparing midurethral tapes to pubovaginal slings*

Basok et al compared the intravaginal sling (IVS) to cadaveric fascia lata, demonstrating similar 12-mo subjective cure rates but significantly higher rates of both persistent urgency urinary incontinence and de novo detrusor overactivity in those patients randomized to fascia lata [30]. Sharifiaghdas and Mortazavi compared the classic TVT to the autologous rectus fascia sling, demonstrating very similar outcomes at midterm follow-up [31]. Tcherniskovsky et al compared a TOT, the Safyre-t, to the autologous rectus fascia sling, reporting similar 12-mo success rates [33]. Finally, two further studies were available in the form of congress abstracts [29,31]. All five studies were of poor methodological quality.

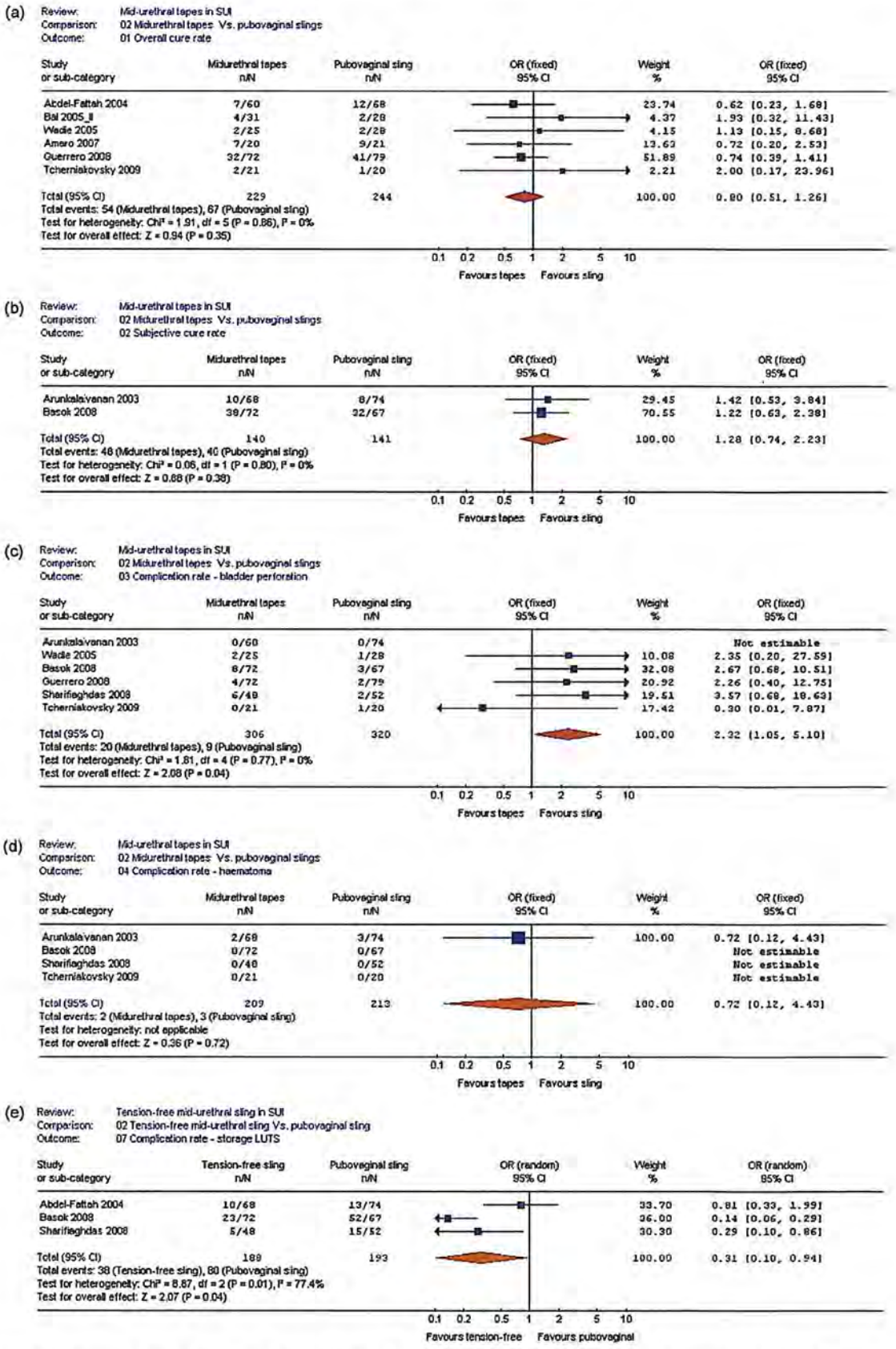


Fig. 3 – Forest plots of comparisons after midurethral tapes and pubovaginal sling: (a) Continence rate according to any definition of cure; (b) subjective continence rate; (c) bladder perforation; (d) pelvic hematoma; (e) storage lower urinary tract symptoms (LUTS); (f) voiding LUTS; (g) reoperation rate. CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

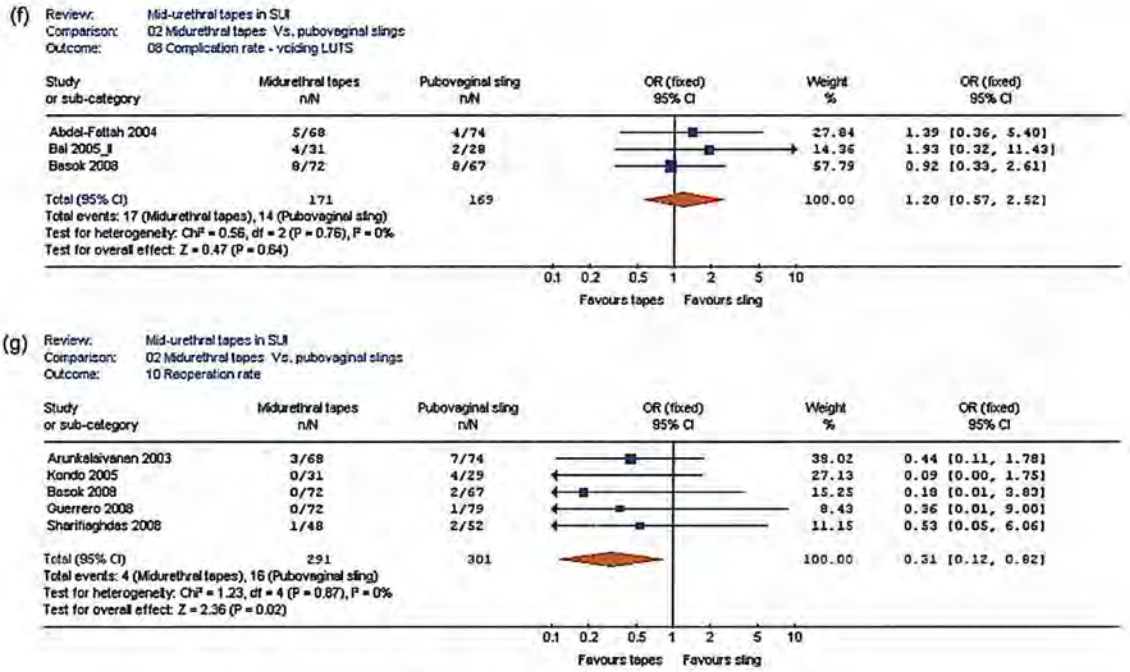


Fig. 3. (Continued).

Supplemental Table 2 in the appendix summarizes continence, complication, and reoperation rates of the RCTs comparing midurethral tapes with pubovaginal slings as the treatment for primary SUI.

Fig. 3 shows the forest plots concerning the meta-analyses of continence, complication, and reoperation rates.

Midurethral tapes and pubovaginal slings had similar efficacy in terms of both overall (OR: 0.80; 95% CI OR: 0.51–1.26; $p = 0.35$; Fig. 3a) and subjective continence rate (OR: 1.28; 95% CI OR: 0.74–2.23; $p = 0.38$; Fig. 3b).

With regard to complication, the risk of intraoperative bladder perforation (OR: 2.32; 95% CI OR: 1.05–5.10; $p = 0.04$; Fig. 3c) were significantly lower in the sling group; pelvic hematoma (OR: 0.72; 95% CI OR: 0.12–4.43; $p = 0.72$; Fig. 3d) was similar in the two procedures. However, midurethral tapes were followed by significantly lower risk of storage LUTS (OR: 0.31; 95% CI OR: 0.10–0.94; $p = 0.04$; Fig. 3e) and reoperation (OR: 0.31; 95% CI OR: 0.12–0.82; $p = 0.02$; Fig. 3g). The prevalence of voiding LUTS (OR: 1.20; 95% CI OR: 0.57–2.52; $p = 0.64$; Fig. 3f) was also similar in the two procedures.

The only RCT of good methodological quality [60] demonstrated similar subjective cure and complication rates between the two surgical techniques.

3.3. *Randomized controlled trials comparing retropubic with transobturator tape*

Specifically, 11 RCTs compared classic TVT with inside-out TOT (TVT-O in 10 [38,39,41–43,47, 48,50,51,55,56] and less invasive free tape in a single one [36]; 9 compared TVT to outside-in TOT (Obtape in two studies [37,40], Monarc in 4 [44–46,49], Iris-TOT in a single one [34], and Obtrix in a single one [53], whereas the implanted devices were not specified in a single study [55]); a single one compared TVT to both TVT-O and Monarc [54]; a single one compared retropubic IVS to outside-in IVS [52], and a single one compared retropubic suprapubic arc (SPARC) sling to Monarc [35].

Supplemental Tables 3 and 4 in the appendix summarize continence, complication, and reoperation rates of the RCTs comparing RT and TOT as the treatment for primary SUI.

Fig. 4 shows the forest plots concerning the meta-analyses of continence, complication, and reoperation rates.

On the whole, overall (OR: 1.02; 95% CI OR: 0.78–1.33; $p = 0.90$; Fig. 4a), and subjective (OR: 0.97; 95% CI OR: 0.75–1.24; $p = 0.80$; Fig. 4c) continence rates were overlapping in the two procedures. Interestingly, among the studies providing subjective outcomes using validated questionnaires, postoperative Urogenital Distress Inventory (UDI-6) (WMD: 0.07; 95% CI: −0.39–0.53; $p = 0.76$; Fig. 4d) and Incontinence Impact Questionnaire (IIQ-7) (WMD: 0.01; 95% CI: −0.22–0.24; $p = 0.95$) scores were similar. Notably, RT were followed by significantly higher objective continence rates (OR: 0.80; 95% CI OR: 0.65–0.99; $p = 0.04$; Fig. 4b). Moreover, a statistically significant difference in favor of TVT was shown when comparing objective continence rates between TVT and inside-out TOT (OR: 0.71; 95% CI OR: 0.52–0.96; $p = 0.03$; Fig. 4b), whereas no difference was found comparing TVT to outside-in TOT (OR: 0.90; 95% CI OR: 0.66–1.22; $p = 0.51$; Fig. 4b). Sensitivity analyses limited to studies of higher methodological quality showed only a nonstatistically significant trend in favor of TVT with regard to objective cure rate (OR: 0.74; 95% CI OR: 0.54–1.01; $p = 0.05$). No differences in subjective and overall continence rates were found in the other sensitivity analyses (Table 2).

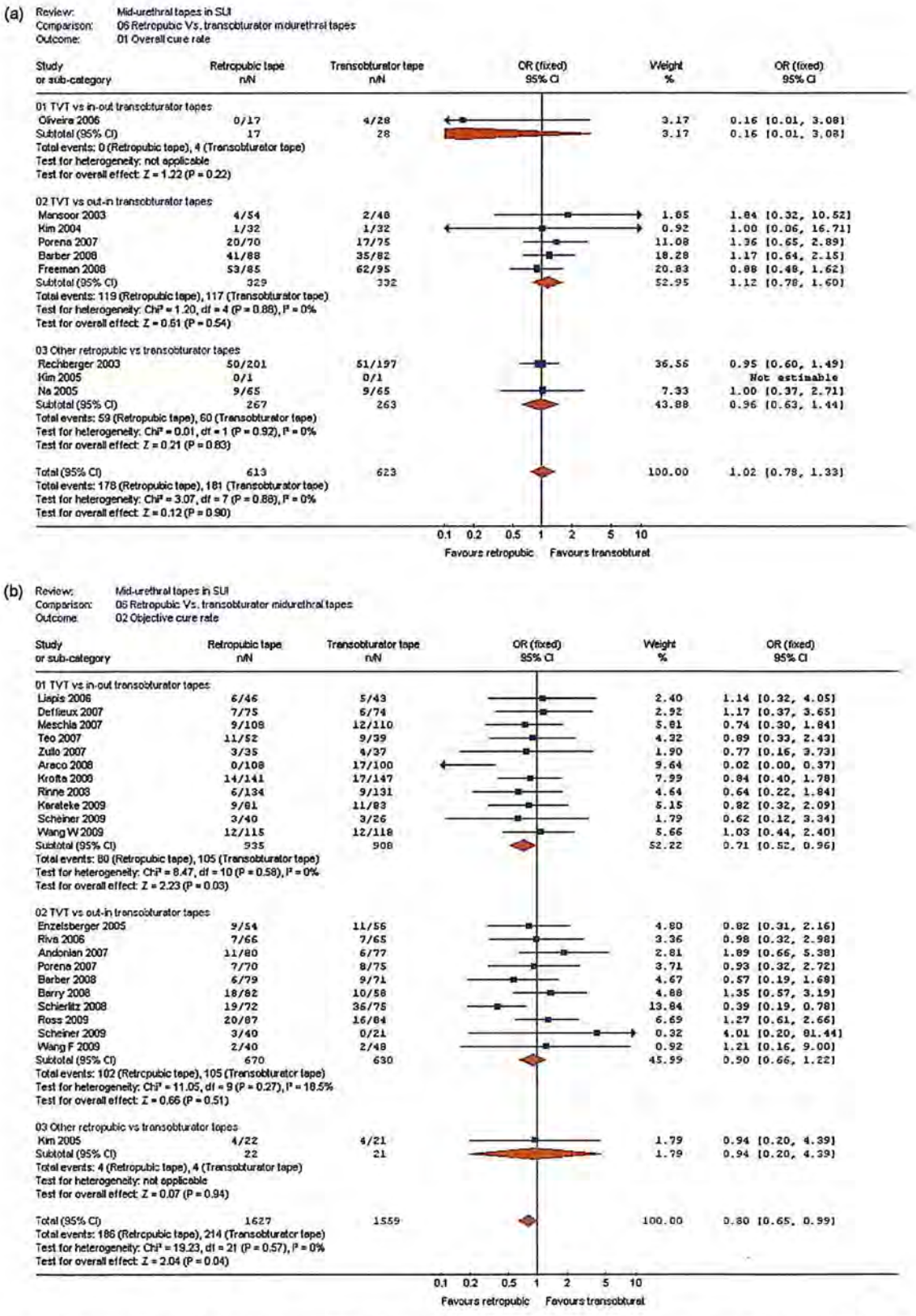


Fig. 4 – Forest plots of comparisons after retropubic tape (RT) and transobturator tape (TOT). (a) Continence rate according to any definition of cure; (b) objective continence rate; (c) subjective continence rate (nonvalidated questionnaire); (d) postoperative Urogenital Distress Inventory–6 score; (e) postoperative Incontinence Impact Questionnaire–7 score; (f) bladder or vaginal perforation; (g) hematoma; (h) vaginal erosion; (i) urinary tract infection; (j) storage lower urinary tract symptoms (LUTS); (k) voiding LUTS; (l) need of clean intermittent catheterization or recatheterization; (m) reoperation rate.

CI = confidence interval; CIC = clean intermittent catheterization; OR = odds ratio; SD = standard deviation; SUI = stress urinary incontinence.

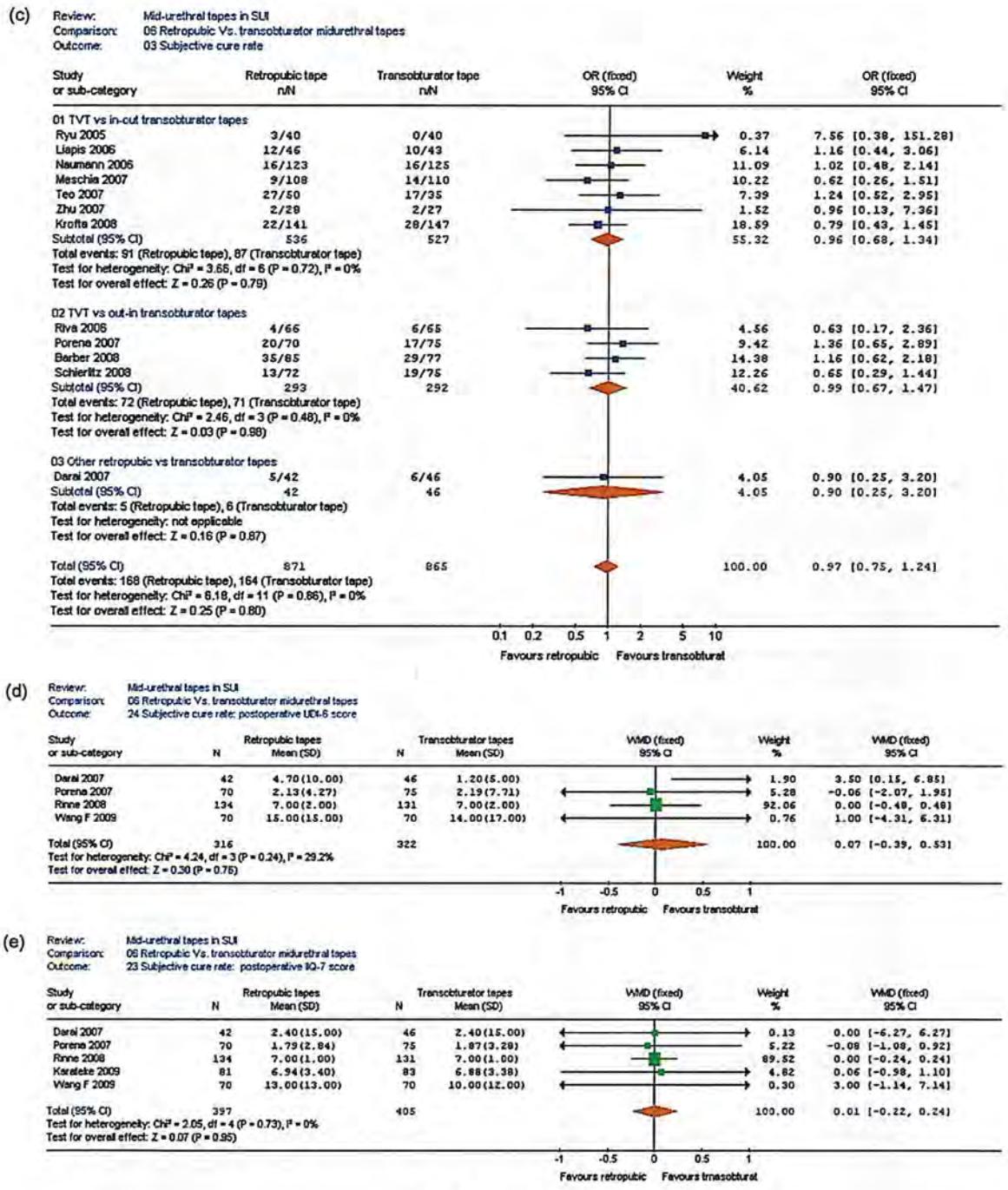
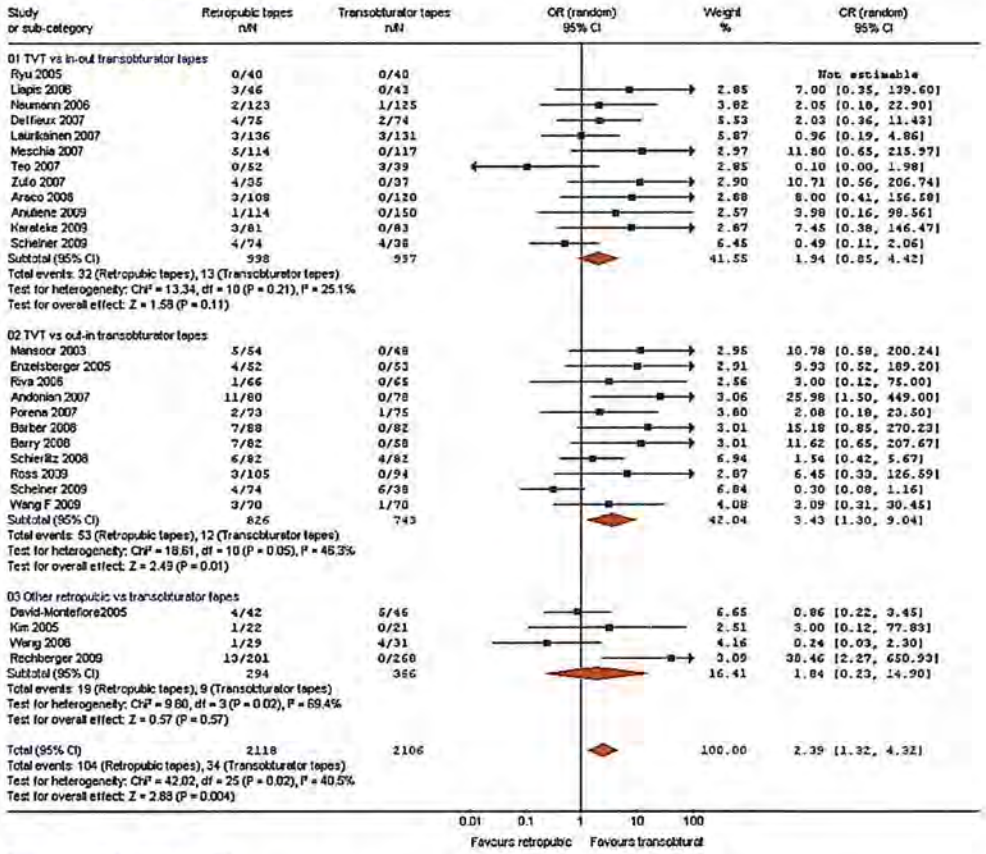


Fig. 4. (Continued)

With regard to complications, not surprisingly, bladder or vaginal perforations (OR: 2.5; 95% CI OR: 1.75–3.57; $p < 0.0001$; Fig. 4f) were significantly more common following RTs, without any significant difference between inside-out and outside-in TOT. Again, as expected, the prevalence of postoperative hematoma was significantly more common following placement of RT (OR: 2.62; 95% CI OR: 1.35–5.08; $p = 0.005$; Fig. 4g). In fact, the rates of vaginal erosion were slightly higher following TOT (OR: 0.64; 95% CI OR: 0.41–0.97; $p = 0.04$; Fig. 4h), due to the studies using Obtape, a device retired from the market due to a high risk of erosions. Finally, the risk of urinary tract infections (OR: 0.95; 95% CI OR: 0.69–1.31; $p = 0.74$; Fig. 4i), the need for clean intermittent catheterization or recatheterization (OR: 1.16; 95% CI OR: 0.84–1.59; $p = 0.37$; Fig. 4l), and the reoperation rate (OR: 1.1; 95% CI OR: 0.75–1.59; $p = 0.62$; Fig. 4m) were fairly similar between RT and TOT. Interestingly, the prevalence of storage LUTS was significantly higher in those patients randomized to RT (OR: 1.35; 95% CI OR: 1.05–1.72; $p = 0.02$; Fig. 4j), without any

(f) Review: Mid-urethral tapes in SUI
Comparison: 06 Retropubic Vs. transobturator midurethral tapes
Outcome: 04 Complication rate - bladder/vaginal perforation



(g) Review: Mid-urethral tapes in SUI
Comparison: 06 Retropubic Vs. transobturator midurethral tapes
Outcome: 05 Complication rate - haematoma

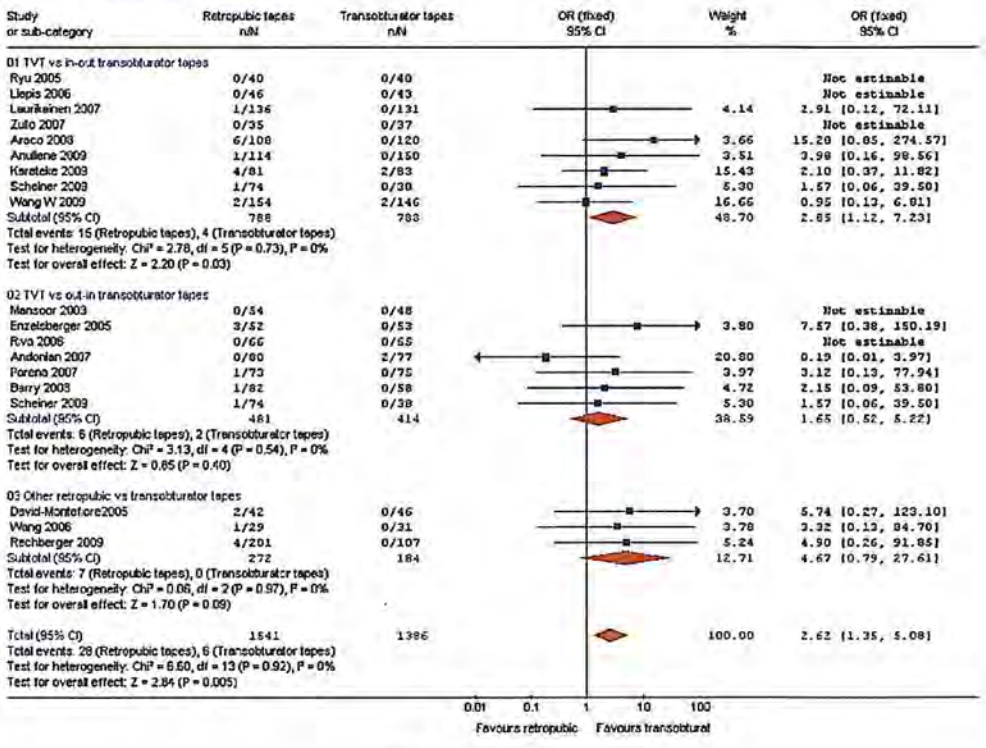
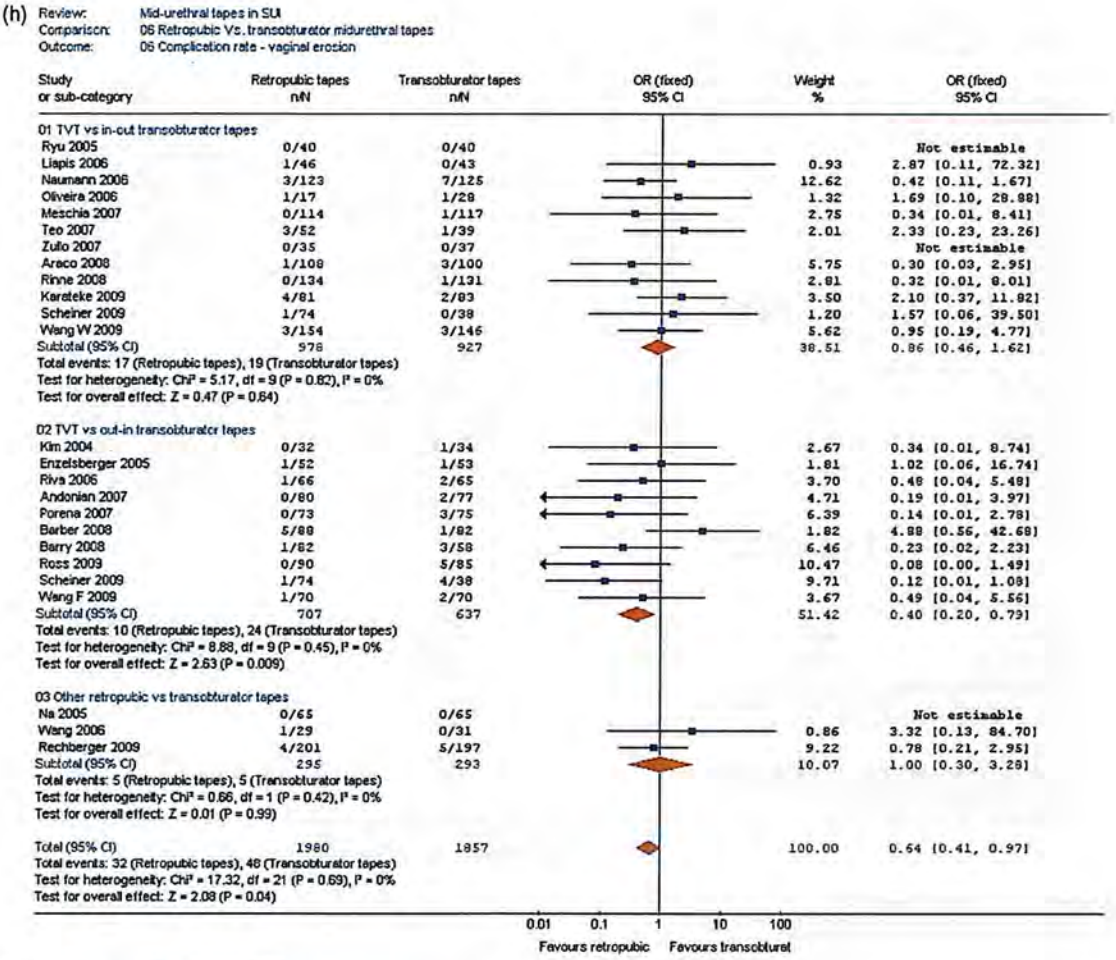


Fig. 4. (Continued)

(h)



(i)

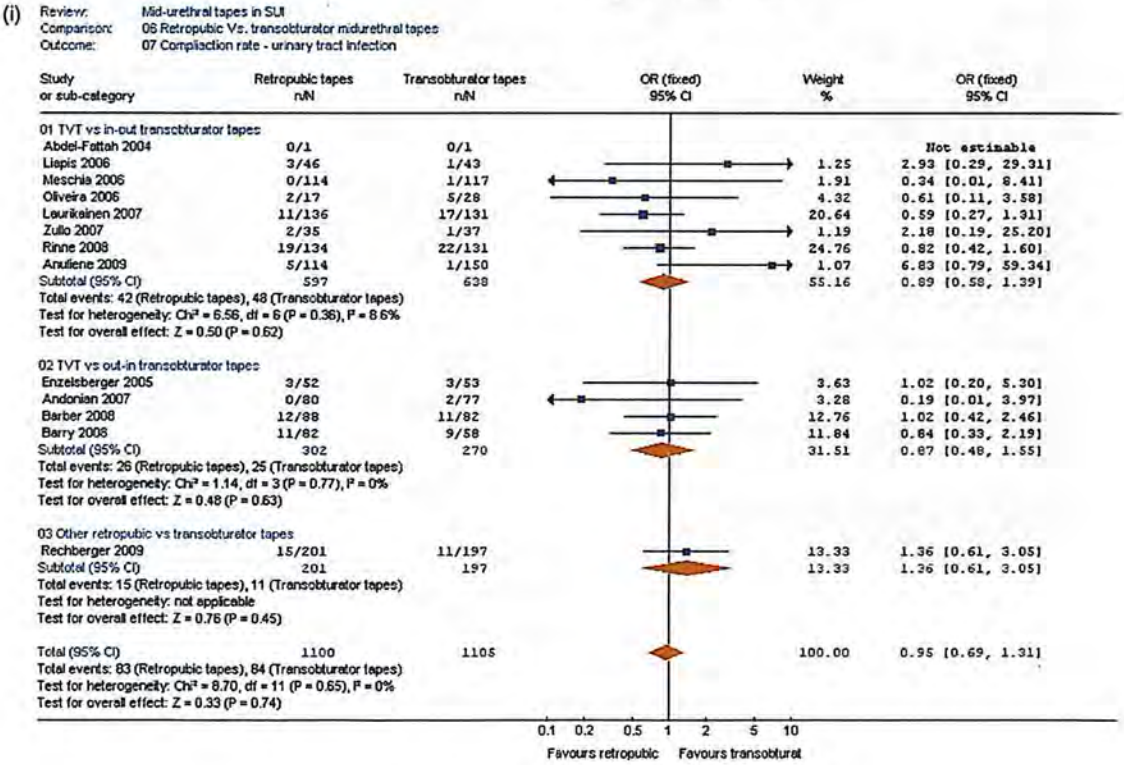
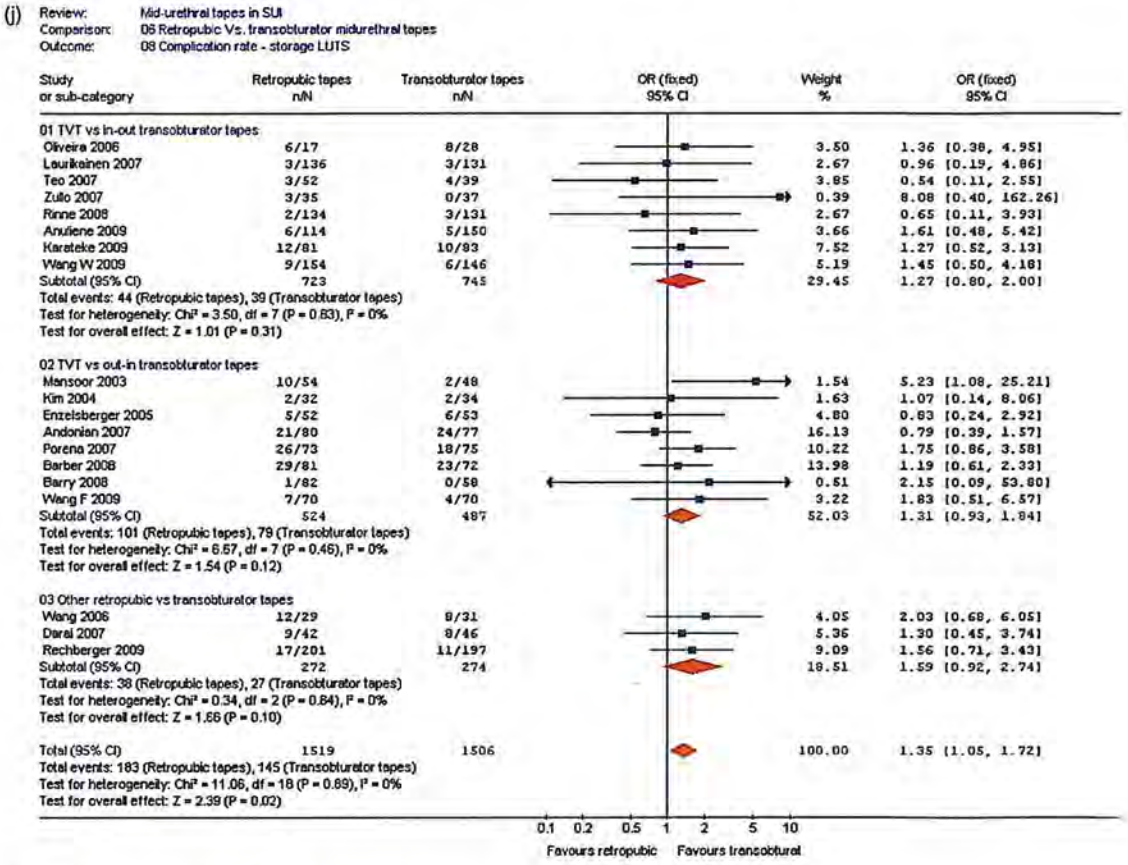


Fig. 4. (Continued)

(j)



(k)

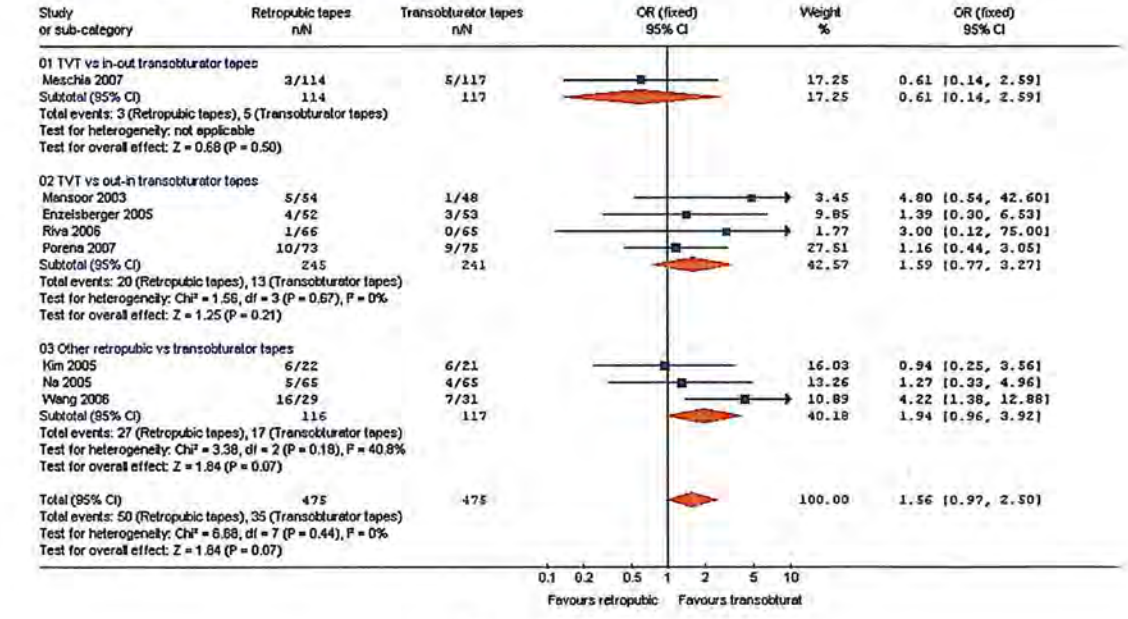
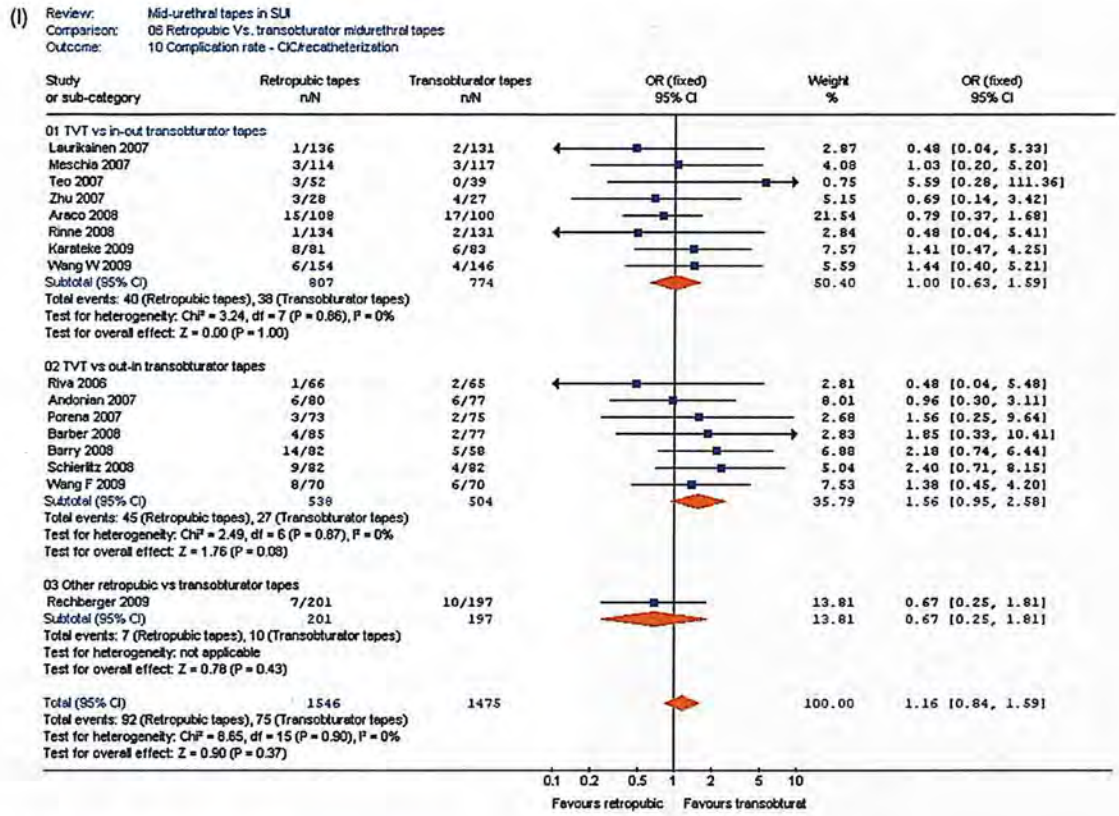


Fig. 4. (Continued)

(l)



(m)

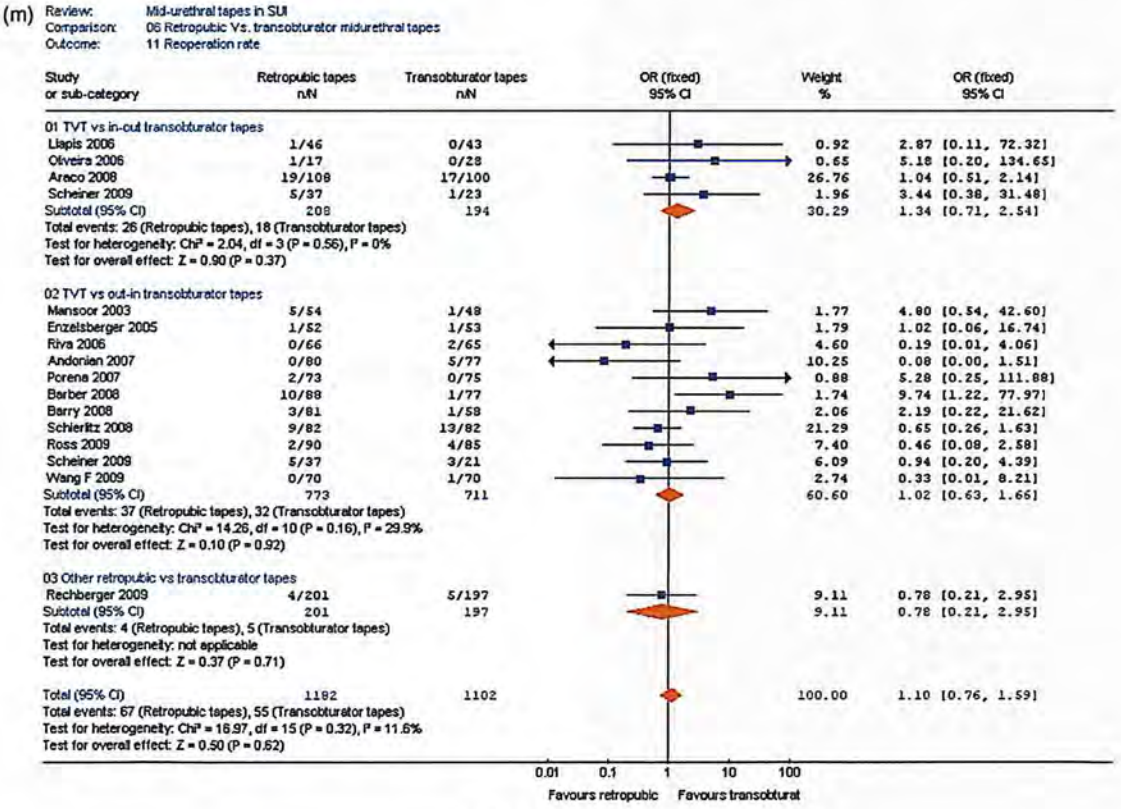


Fig. 4. (Continued).

Table 2 – Comparisons after retropubic tape and transobturator tape: Meta-analysis of all the randomized controlled trials (RCTs) and sensitivity analyses for high-quality RCTs

Retropubic vs transobturator tapes	All RCTs					High-quality RCTs					
	RCT	Participants	OR	95% CI of OR	*p* value	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
Continence rate											
Any definition of continence	9	1236	1.02	0.78–1.33	0.90	None	2	315	1.24	0.78–1.99	0.36	None
Objective continence rate	22	3186	0.80	0.65–0.99	0.04	RT	9	1481	0.74	0.54–1.01	0.05	None
Subjective continence rate	12	1736	0.97	0.75–1.24	0.80	None	5	727	0.95	0.66–1.36	0.77	None
Postoperative UDI-6 score	4	638	0.07*	−0.39–0.53	0.76	None	2	410	0*	−0.47–0.47	0.99	None
Postoperative IIQ-7 score	5	802	0.01*	−0.22–0.24	0.95	None	3	574	0*	−0.23–0.23	0.99	None
Adverse events											
	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
Bladder/vaginal perforation	27	4224	2.5	1.75–3.57	<0.0001	TOT	10	1624	2.52	1.41–4.52	0.002	TOT
Hematoma	19	2927	2.62	1.35–5.08	0.005	TOT	5	711	2.54	0.72–8.96	0.15	None
Vaginal erosion	25	3837	0.64	0.41–0.97	0.04	RT	8	1285	0.79	0.37–1.68	0.54	None
Urinary tract infection	13	2205	0.95	0.69–1.31	0.74	None	4	774	0.81	0.53–1.25	0.34	None
Storage LUTS	19	3025	1.35	1.05–1.72	0.02	TOT	7	1129	1.44	0.99–2.09	0.06	None
Voiding LUTS	8	950	1.56	0.97–2.5	0.07	None	3	439	1.59	0.85–2.97	0.15	None
CIC/recatheterization	16	3021	1.16	0.84–1.59	0.37	None	8	1456	1.29	0.75–2.22	0.35	None
Reoperation rate	16	2284	1.1	0.75–1.59	0.62	None	4	652	1.24	0.66–2.35	0.5	None

CI = confidence interval; CIC = clean intermittent catherization; IIQ = Incontinence Impact Questionnaire; LUTS = lower urinary tract symptoms; OR = odds ratio; RT = retropubic tape; TOT = transobturator tape; UDI = Urogenital Distress Inventory.
* Weight mean difference.

significant difference between inside-out and outside-in TOT. A nonstatistically significant difference in favor of TOT was found for voiding LUTS (OR: 1.56; 95% CI OR: 0.97–2.5; $p = 0.07$; Fig. 4k). In sensitivity analyses limited to studies of higher methodological quality, only a nonstatistically significant trend in favor of TOT was found for storage LUTS (OR: 1.44; 95% CI OR: 0.99–2.09; $p = 0.06$) and voiding LUTS (OR: 1.59; 95% CI OR: 0.85–2.97; $p = 0.15$). Similarly, with regard to the risk of all the other complications and reoperation, no differences were identified in the other sensitivity analyses (Table 2).

3.4. *Randomized controlled trials comparing different transobturator midurethral tapes*

But and Fagenelj randomized 120 patients to TVT-O or Monarc, demonstrating similar objective and subjective continence rates at 4-mo follow-up [58]. However, a significantly higher number of vaginal perforations occurred in the patients randomized to Monarc (0% vs 15%), and the inside-out procedure was significantly more painful than the outside-in one in the first 6 h after surgery. Similarly, Liapis et al evaluated 114 patients randomized to TVT-O ($n = 61$) or Monarc ($n = 53$), reporting fairly similar 12-mo continence and complication rates [59]. Similar data were reported by Houwert et al in a congress abstract [57]. Only the study by But and Fagenelj [58] was of good methodological quality.

Supplemental Table 5 in the appendix summarizes continence, complication, and reoperation rates of the RCTs, comparing different TOT as the treatment for primary SUI.

Fig. 5 shows the forest plots concerning the meta-analyses of objective continence and the rates of urinary tract infections (UTIs).

Both objective continence rate (OR: 1.96; 95% CI OR: 0.84–4.53; $p = 0.12$; Fig. 5a) and UTIs (OR: 1.91; 95% CI OR: 0.73–5.01; $p = 0.19$; Fig. 5b) were similar in the two procedures.

3.5. *Publication bias*

Funnel plots of all the studies used in this meta-analysis were generated for all the evaluated comparisons. Only eight studies [41,49,54,61–65] lay outside the 95% CI with an even distribution about the vertical, suggesting little evidence of publication bias (see Supplemental Figs. 1–4 in the appendix).

3.6. *Discussion*

Open retropubic colposuspension, autologous fascial slings, and midurethral tape are recommended for the management of primary SUI, according to the recent recommendations of the 4th International Consultation on Incontinence [66]. Significant changes in clinical practice have been observed over the past decade, with the number of colposuspensions and autologous slings declining considerably, mainly in favor of TVT [67].

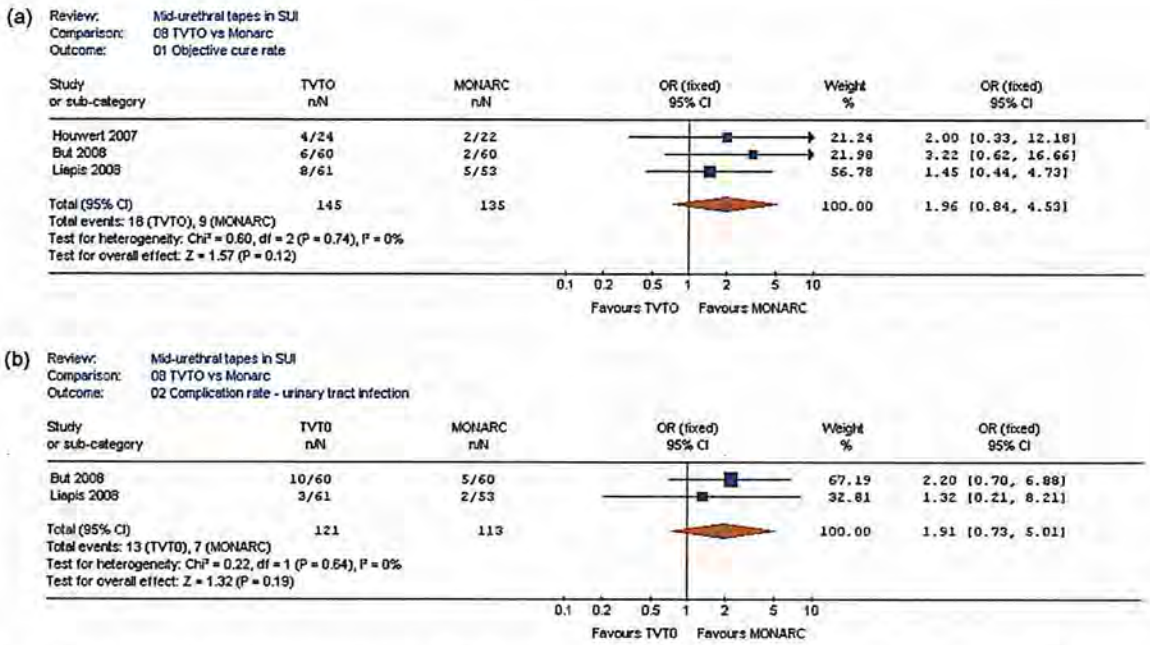


Fig. 5 – Forest plots of comparisons after different transobturator tapes (TOTs). (a) Objective continence rate; (b) urinary tract infection. CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

These changes in practice, however, seem to be proceeding in advance of high-quality evidence, or at least based only on short- and midterm follow-up evidence. Because of the large number of RCTs available, many with conflicting results, and because of the demand for evidence-based medicine, several meta-analyses of RCTs have been reported [11,12,16,68–71], with only three focused on the comparison of midurethral tapes with other surgical treatments [11,12,16]. Following the publication of several other RCTs and follow-up extensions on some of the previously available studies, we elected to update our two previous meta-analyses. We found that midurethral tapes were followed by significantly higher overall and objective continence rates than Burch colposuspension, although bladder perforations were more common after RT. Although midurethral and pubovaginal slings were reconfirmed to be similarly effective in the treatment of SUI, pubovaginal slings were found to be more frequently associated with storage LUTS, although intraoperative bladder perforations were less common with pubovaginal slings. Notably, classic TVT was shown to be followed by significantly higher objective continence rates than TOT, but the data were not reconfirmed in sensitivity analyses limited to high-quality trials; however no difference was noted in subjective continence rates. What is evident is that such benefits are basically at the cost of higher risks of intraoperative complications such as bladder or vaginal perforations and postoperative hematoma. Furthermore, storage LUTS was also slightly more common after RT. No new RTCs comparing different RT have been published since 2007. With regard to TOT, the available data from two RCTs failed to show any significant difference between two TOT (ie, TVT-O and Monarc). Finally, no RCT evaluating readjustable slings or single-incision tapes were available.

On the whole, the figures of the meta-analysis seem to support the increasing role of midurethral tapes and, specifically, of TOT in the setting of the primary treatment of the patients with SUI. However, those data raise several concerns regarding outcome measures, reporting of complications, and follow-up. Overall, the present meta-analysis included a significant number of RCTs with good methodological quality as judged by the Jadad score, and it generated consistent results in all the sensitivity analyses. However, even considering the lack of statistical power in most studies overcome by the meta-analysis strategy, and assuming uniformity of surgical techniques in the different RCTs, the variations in the outcome measures used, the length of follow-up, and the handling of cases lost to follow-up still remain significant concerns. In particular, when considering outcome measures, the definitions of cure used can affect the study results significantly. For example, evaluating data from the UK TVT trial, Hilton demonstrated success rates lower than 30% for both TVT and Burch colposuspension applying both subjective and objective continence rates, whereas >60% of the same patients could be considered cured based on the absence of urodynamic SUI or on a negative pad test [72]. Similarly, Albo et al, reporting the data of the Stress Incontinence Surgical Treatment Efficacy Trial, demonstrated that about 15% of the patients in each arm have to be considered as surgical failures based on the presence of a positive pad test. However, using more stringent criteria such as the concomitant presence of no self-reported symptoms of SUI, no SUI episodes recorded in a 3-d diary, a negative

urinary stress test, and no retreatment for SUI, about 40% of the patients randomized to pubovaginal sling and 60% of those having Burch colposuspension were surgical failures [73]. Consequently, standardized criteria to report patients' outcomes are desirable.

With regard to the tools used to assess outcomes, we found that only 21 RCTs of 76 used validated questionnaires to evaluate subjective cure rates, the impact of SUI on quality of life, and the association of SUI and SUI treatments with LUTS and sexual function. In fact, a multitude of different tools were applied (Bristol Female Lower Urinary Tract Symptoms questionnaire, EQ-5D, King's College Health Questionnaire, Incontinence Severity Index, International Consultation on Incontinence-Short Form, Incontinence Impact Questionnaire score, Incontinence Quality of Life score, Patient's Global Expression of Severity, Medical Outcomes Study 12-Item, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, Short Form Urinary Distress Inventory, Women Irritative Prostate Symptoms Score), making comparisons very hard. A standardized assessment, perhaps applying the International Consultation on Incontinence modular questionnaire, is highly recommended.

With regard to complications, a very limited number of major complications was observed in the evaluated RCTs, although bowel, vascular, and nerve injuries, necrotizing fasciitis, ischiorectal abscess, urethrovaginal fistulas, sepsis, and patient deaths have been reported after placement of RT and TOT. Specifically, Deng et al reported on the prevalence of major complications in the US Food and Drug Administration's Manufacturer and User Facility Device Experience database, identifying 32 cases of vascular injuries, 33 bowel injuries, and 8 patient deaths after TVT placement [74]. Due to the low prevalence of such complications, surgical series and, above all, national or manufacturer registries should be considered more reliable, and their implementation should be strongly recommended. Moreover, most of the complications reported in the available RCTs were intraoperative ones, with a limited number of studies providing data on the intermediate- and long-term functional sequelae. That is of outmost importance because some underreported complications, including storage and voiding LUTS, can be disabling for the affected patients, whereas some intraoperative complications such as bladder injury during placement of RT are of little or no implication provided they are promptly recognized and treated.

With regard to follow-up duration, only two studies reported data at follow-up of ≥60 mo [26,27], which clearly does not allow either the durability of efficacy or the presence of long-term morbidity and functional complications to be adequately evaluated. That is clearly a major deficit in our knowledge base. Moreover, in most studies, patients lost to follow-up were simply deleted from the analyses, and their outcomes were assumed to be similar to those of the whole cohort. This approach has to be regarded as incorrect, and assumptions should be made on their outcomes (eg, considering all study dropouts as cured or as failures, or carrying forward the last postoperative data), in order to provide more realistic estimations of the results [27].

4. Conclusions

The literature summarized in this meta-analysis showed RT to be significantly more effective than colposuspension but to have a higher risk of intraoperative bladder perforation. Pubovaginal slings and midurethral tapes were shown to be similarly effective in the treatment of SUI, with storage LUTS more prevalent following pubovaginal slings, and intraoperative bladder perforation more common with RT. Classic TVT appeared to be followed by significantly higher objective continence rates than TOT but with no difference in subjective continence rates and at the cost of higher risks of intraoperative complications and storage LUTS. Finally, no significant differences were identified in the studies comparing different TOT head to head. Statistically speaking, many trials were of good methodological quality, and sensitivity analyses limited to only high-quality studies reconfirmed most of the previously mentioned findings. From a clinical point of view, the heterogeneity in outcome measures and the lack of RCTs with long-term follow-up represent significant deficits in the evidence base and limit our ability to counsel patients about longer term outcomes. Standardization of outcome measures used, handling of data with regard to patients lost to follow-up, and consensus on what type of cure we are discussing in trials with a follow-up of ≥5 yr are clearly needed.

Author contributions: Giacomo Novara had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Novara, Ficarra, Artibani
Acquisition of data: Novara, Ficarra.
Analysis and interpretation of data: Novara, Ficarra, Artibani.
Drafting of the manuscript: Novara.
Critical revision of the manuscript for important intellectual content: Barber, Chapple, Constantini, Hilton, Nilsson, Waltregny.
Statistical analysis: Novara.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: None.
Other (specify): None.

Financial disclosures: I certify that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Giacomo Novara and Walter Artibani have no current financial interests to declare; they were both previously investigators in a randomized control trial (RCT) of surgery for stress urinary incontinence (SUI) funded by Gynecare (2005–2006). Paul Hilton has no current financial interests to declare; he was previously the lead investigator in a RCT of surgery for SUI funded by Gynecare (1998–2003) and received research funding from Gynae Ideas for development work into devices for the treatment of SUI and pelvic organ prolapse (2001–2003); he has also received reimbursement of travel expenses to attend meetings in relation to these studies. He was the guideline development group lead for the National Institute for Health and Clinical Excellence clinical guideline on urinary incontinence in women (2004–2007), a member of the "Surgery for Incontinence in Women" group within the 4th International Consultation on Incontinence

(2007–2009), and currently is a member of the Clinical Evaluations and Trials Prioritisation Group of the National Institute for Health Research Health Technologies Assessment programme (2008–present). David Waltregny is a consultant for Ethicon. The University of Liège owns the TVT-Obturator patent.

Funding/Support and role of the sponsor: None.

Appendix A. Supplementary data

Supplemental tables and figures accompanying this article can be found in the online version at doi:10.1016/j.eururo.2010.04.022 and via www.europeanurology.com.

References

[1] Botlero R, Urquhart DM, Davis SR, Bell RJ. Prevalence and incidence of urinary incontinence in women: review of the literature and investigation of methodological issues. Int J Urol 2008;15:230–4.

[2] Serati M, Salvatore S, Uccella S, et al. Surgical treatment for female stress urinary incontinence: what is the gold-standard procedure? Int Urogynecol J 2009;20:619–21.

[3] Hu TW, Wagner TH, Bentkover JD, et al. Costs of urinary incontinence and overactive bladder in the United States: a comparative study. Urology 2004;63:461–5.

[4] Turner DA, Shaw C, McGrother CW, et al. The cost of clinically significant urinary storage symptoms for community dwelling adults in the UK. BJU Int 2004;93:1246–52.

[5] Abrams P, Andersson KE, Birder L, et al. Recommendations of the International Scientific Committee: evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence. In: Abrams P, Cardozo L, Khoury S, Wein A, eds. Incontinence. 4th ed. Plymouth, UK: Health Publications; 2009. p. 1767–854.

[6] Rovner ES, Lebed BD. Stress incontinence surgery: which operation when? Curr Opin Urol 2009;19:362–7.

[7] Norton P, Brubaker L. Urinary incontinence in women. Lancet 2006;367:57–67.

[8] Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.

[9] Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1043–7.

[10] Bullock TL, Ghoniem G, Klutke CG, Staskin DR. Advances in female stress urinary incontinence: midurethral slings. BJU Int 2006;98 (Suppl 1):32–40.

[11] Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W. Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol 2007;52: 663–79.

[12] Novara G, Galfano A, Boscolo-Berto R, et al. Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol 2008;53:288–309.

[13] Ward KL, Hilton P, UK and Ireland TVT Trial Group. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol 2004;190:324–31.

[14] Paraiso MF, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstet Gynecol 2004;104:1249–58.

[15] The Cochrane Collaboration open learning material. Maintaining your review: how to update your review. Cochrane Collaboration Web site. http://www.cochrane-net.org/openlearning/html/mod19-3.htm.

[16] Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev 2009. p. CD006375.

[17] Phillips B, Ball C, Sackett D, et al. Levels of evidence and grades of recommendation. Oxford Centre for Evidence-Based Medicine Web site. http://www.cebm.net/levels_of_evidence.asp.

[18] Jadad AR. Randomised controlled trials. London, UK: BMJ Publishing Group; 1998.

[19] Rothstein HR, Sutton AJ, Borenstein M. Publication bias in meta-analysis: prevention, assessment and adjustment. Chichester, UK: John Wiley; 2005.

[20] Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009;151:264–9.

[21] Han WHC. Burch colposuspension or tension-free vaginal tape for female urinary incontinence [abstract]? Int Urogynecol J 2001; 12(Suppl 3):S23.

[22] Koelbl H, Halaska M, Ostermann S, Lautenschlaeger C. Burch colposuspension and TVT—perioperative results of a prospective randomized trial in patients with genuine stress incontinence [abstract]. Neurourol Urodyn 2002;21:327.

[23] Adile B, Granese R, Lo Bue A, Gugliotta G, Cardella AM, Adile C. A prospective randomized study comparing laparoscopic Burch versus TVT. Short and long term follow-up [abstract]In: Proceedings of the 33rd Annual Meeting of the International Continence Society; October 5–9; Florence, Italy; 2003.

[24] Mirosh M, Epp A. TVT vs laparoscopic Burch colposuspension for the treatment of stress urinary incontinenceIn: Proceedings of the 35th Annual Meeting of the International Continence Society; August 28–September 2; Montreal, Canada; 2005, Abstract 640.

[25] Drahoradova P, Masata J, Martan A, Svabik K. Comparative development of quality of life between TVT and Burch colposuspension. In: Proceedings of the 34th Annual Meeting of the International Continence Society and the International UroGynecological Association; August 25–27; Paris, France; 2004, Abstract 278.

[26] Jelovsek JE, Barber MD, Karram MM, Walters MD, Paraiso MF. Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008;115:219–25.

[27] Ward KL, Hilton P, UK and Ireland TVT Trial Group. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008;115:226–33.

[28] Sivaslioglu AA, Caliskan E, Dolen I, Haberal A. A randomized comparison of transobturator tape and Burch colposuspension in the treatment of female stress urinary incontinence. Inter Urogynecol J 2007;18:1015–9.

[29] Kondo A, Isobe Y, Kimura K, Kamihira O, Matsuura O. A randomized controlled trial of tension-free vaginal tape vs pubovaginal sling: cure rates and QOL improvementIn: Proceedings of the 35th Annual International Continence Society; August 28–September 2; Montreal, Canada; 2005, Abstract 629.

[30] Basok EK, Yildirim A, Atsu N, Basaran A, Tokuc R. Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates. Urol Int 2008;80:46–51.

[31] Sharifiaghdas F, Mortazavi N. Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary

stress incontinence: a medium-term follow-up. Med Princ Pract 2008;17:209–14.
[32] Guerrero K, Whareham K, Watkins A, Ismail S, Lucas M, Emery S. A randomised control trial comparing TVT, Pelvicol and autologous fascial slings for the management of stress urinary incontinence in women. In: Proceedings of the 38th Annual Meeting of the International Continence Society; October 20–24; Cairo, Egypt; 2008, Abstract 1.
[33] Tcherniakovsky M, Fernandes CE, Bezerra CA, et al. Comparative results of two techniques to treat stress urinary incontinence: synthetic transobturator and aponeurotic slings. Intern Urogynecol J 2009;20:961–6.
[34] Kim J, Baek U, Kwon S, et al. The efficacy of Iris procedure in stress urinary incontinence: comparison with TVT and SPARC (Abstract). In: Proceedings of the 34th annual meeting of the International Continence Society and the International UroGynecological Association; August 25–27; Paris, France; 2004, Abstract 313.
[35] Kim Y-W, Na Y-G, Sul C-K. Randomized prospective study between pubovaginal sling using SPARC sling system and MONARC sling system for the treatment of female stress urinary incontinence: short term results [in Korean]. Korean J Urol 2005;46:1078–82.
[36] Naumann G, Lobodasch K, Bettin S, Meyer P, Koelbl H. Tension free vaginal tape (TVT) vs less invasive free tape (LIFT)—a randomized multicentric study of suburethral sling surgery. Int Urogynecol J 2006;17(Suppl 2):S94–5, Abstract 062.
[37] Andonian S, St-Denis B, Lemieux M-C, Corcos J. Prospective clinical trial comparing Obtape® and DUPS to TVT: one-year safety and efficacy results. Eur Urol 2007;52:245–52.
[38] Deffieux X, Daher N, Mansoor A, et al. Tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a multicenter randomized controlled trial [abstract]. Int Urogynecol J 2007;18(Suppl 1), S19:33.
[39] Meschia M, Bertozzi R, Pifarotti P, et al. Peri-operative morbidity and early results of a randomized trial comparing TVT and TVT-O. Int Urogynecol J 2007;18:1257–61.
[40] Porena M, Costantini E, Frea B, et al. Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. Eur Urol 2007; 52:1481–91.
[41] Teo R, Moran P, Mayne C, Tincello D. Randomised trial of tension-free vaginal tape and transobturator tape for the treatment of urodynamic stress incontinence in women. In: Proceedings of the 37th Annual Meeting of the International Continence Society; August 20–24; Rotterdam, Netherlands; 2007, Abstract 283.
[42] Zhu L, Lang J, Hai N, Wong F. Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. Int J Gynaecol Obstet 2007;99:14–7.
[43] Araco F, Gravante G, Sorge R, et al. TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:917–26.
[44] Barber MD, Kleeman S, Karram MM, et al. Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2008;111:611–21.
[45] Barry C, Lim YN, Muller R, et al. A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study. Int Urogynecol J 2008;19:171–8.
[46] Freeman R, Holmes D, Smith P, et al. Is trans-obturator tape (TOT) as effective as tension-free vaginal tape (TVT) in the treatment of women with urodynamic stress incontinence? Results of a multicentre RCT. In: Proceedings of the 38th Annual Meeting of the International Continence Society; October 20–24; Cairo, Egypt; 2008, Abstract 3.
[47] Krofta L, Feyereisl J, Otčenášek M, et al. Tension free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence [in Czech]. Ceska Gynekol 2008;73: 231–9.
[48] Rinne K, Laurikainen E, Kivela A, et al. A randomized trial comparing TVT with TVT-O: 12-month results. Int Urogynecol J 2008;19: 1049–54.
[49] Schierlitz L, Dwyer PL, Rosamilia A, et al. Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial. Obstet Gynecol 2008;112:1253–61.
[50] Aniuliene R. Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence. Medicina (Kaunas) 2009;45: 639–43.
[51] Karateke A, Haliloglu B, Cam C, Sakalli M. Comparison of TVT and TVT-O in patients with stress urinary incontinence: short-term cure rates and factors influencing the outcome. A prospective randomised study. Aust N Z J Obstet Gynaecol 2009;49:99–105.
[52] Rechberger T, Futyma K, Jankiewicz K, Adamiak A, Skorupski P. The clinical effectiveness of retropubic (IVS-02) and transobturator (IVS-04) midurethral slings: randomized trial. Eur Urol 2009;56: 24–30.
[53] Ross S, Robert M, Swaby C, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence a randomized controlled trial. Obstet Gynecol 2009;114:1287–94.
[54] Scheiner D, Betschart C, Werder H, Fink D, Perucchini D. Retropubic TVT vs transobturator outside-in TOT and inside-out TVT-O—one-year results from our prospective randomized studyIn: Proceedings of the 39th Annual Meeting of the International Continence Society; September 29–October 3; San Francisco, CA. 2009, Abstract 4.
[55] Wang F, Song Y, Huang H. Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China. Arch Gynecol Obstet 2010;281:279–86.
[56] Wang W, Zhu L, Lang J. Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence. Int J Gynaecol Obstet 2009;104:113–6.
[57] Houwert M, Vos MC, Vervest HAM. Transobturator tape (TOT), inside-out versus outside-in approaches: outcome after 1 year. Int Urogynecol J 2007;18(Suppl 1):S33, Abstract 056.
[58] But I, Faganelj M. Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study. Int Urogynecol J 2008;19:857–61.
[59] Liapis A, Bakas P, Creatsas G. Monarc vs TVT-O for the treatment of primary stress incontinence: a randomized study. Int Urogynecol J 2008;19:185–90.
[60] Arunkalaivanan AS, Barrington JW. Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence: a questionnaire-based study. Int Urogynecol J Pelvic Floor Dysfunct 2003;14: 17–23.
[61] Abdel-Fattah M, Barrington JW, Arunkalaivanan AS. Pelvicol™ pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. Eur Urol 2004;46:629–35.
[62] Valpas A, Kivela A, Penttinen J, Kujansuu E, Haarala M, Nilsson CG. Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence. Obstet Gynecol 2004;104:42–9.
[63] Enzelsberger H, Schalupny J, Heider R, et al. TVT versus TOT—a prospective randomized study for the treatment of female

stress urinary incontinence at a follow-up of 1 year. Geburtshilfe Frauenheilkunde 2005;65:506–11.

[64] Riva D, Saccà V, Tonta A, et al. T.V.T. versus T.O.T. A randomized study at 1-year follow-up. Int J Urogynecol 2006;17(Suppl 2):S293, Abstract 060.

[65] Wang AC, Lin YH, Tseng LH, Chih SY, Lee CJ. Prospective randomized comparison of transobturator suburethral sling (Monarc) vs suprapubic arc (Sparc) sling procedures for female urodynamic stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2006; 17:439–43.

[66] Smith ARB, Dmochowski R, Hilton P, et al. Surgery for urinary incontinence in women. In: Abrams P, Cardozo L, Khoury S, Wein A, eds. Incontinence. 4th ed. Plymouth, UK: Health Publications; 2009. p. 1191–272.

[67] Hilton P. Long-term follow-up studies in pelvic floor dysfunction: the Holy Grail or a realistic aim? BJOG 2008;115:135–43.

[68] Bezerra CA, Bruschini H, Cody DJ. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst Rev 2005. p. CD001754.

[69] Dean NM, Ellis G, Wilson PD, Herbison GP. Laparoscopic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev 2006. p. CD002239.

[70] Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007; 114:522–31.

[71] Lapitan MC, Cody JD, Grant A. Open retropubic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev 2009. p. CD002912.

[72] Hilton P. Trials of surgery for stress incontinence—thoughts on the 'Humpty Dumpty' principle. BJOG 2002;109:1081–8.

[73] Albo ME, Richter HE, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med 2007;356:2143–55.

[74] Deng DY, Rutman M, Raz S, Rodriguez LV. Presentation and management of major complications of midurethral slings: are complications under-reported? Neurourol Urodyn 2007;26:46–52.

UROGYNECOLOGY

Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

Megan O. Schimpf, MD; David D. Rahn, MD; Thomas L. Wheeler, MD, MSPH; Minita Patel, MD, MS; Amanda B. White, MD; Francisco J. Orejuela, MD; Sherif A. El-Nashar, MBBCh, MS; Rebecca U. Margulies, MD; Jonathan L. Gleason, MD; Sarit O. Aschkenazi, MD; Mamta M. Mamik, MD; Renée M. Ward, MD; Ethan M. Balk, MD, MPH; Vivian W. Sung, MD, MPH; for the Society of Gynecologic Surgeons Systematic Review Group

OBJECTIVE: Understanding the long-term comparative effectiveness of competing surgical repairs is essential as failures after primary interventions for stress urinary incontinence (SUI) may result in a third of women requiring repeat surgery.

STUDY DESIGN: We conducted a systematic review including English-language randomized controlled trials from 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling or Burch urethropexy. When at least 3 randomized controlled trials compared the same surgeries for the same outcome, we performed random effects model metaanalyses to estimate pooled odds ratios (ORs).

RESULTS: For midurethral slings (MUS) vs Burch, metaanalysis of objective cure showed no significant difference (OR, 1.18; 95% confidence interval [CI], 0.73–1.89). Therefore, we suggest either intervention; the decision should balance potential adverse events (AEs) and concomitant surgeries. For women considering pubovaginal sling vs Burch, the evidence favored slings for both subjective and objective cure. We recommend pubovaginal sling to maximize cure outcomes. For pubovaginal slings vs MUS, metaanalysis of subjective cure favored MUS (OR, 0.40; 95% CI, 0.18–0.85). Therefore, we recommend MUS. For obturator slings vs retropubic MUS, metaanalyses for both objective (OR, 1.16; 95% CI, 0.93–1.45) and subjective cure (OR, 1.17; 95% CI, 0.91–1.51) favored retropubic slings but were not significant. Metaanalysis of satisfaction outcomes favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52–1.13). AEs were variable between slings; metaanalysis showed overactive bladder symptoms were more common following retropubic slings (OR, 1.413; 95% CI, 1.01–1.98, $P = .046$). We recommend either retropubic or obturator slings for cure outcomes; the decision should balance AEs. For minislings vs full-length MUS, metaanalyses of objective (OR, 4.16; 35% CI, 2.15–8.05) and subjective (OR, 2.65; 95% CI, 1.36–5.17) cure both significantly favored full-length slings. Therefore, we recommend a full-length MUS.

CONCLUSION: Surgical procedures for SUI differ for success rates and complications, and both should be incorporated into surgical decision-making. Low- to high-quality evidence permitted mostly level-1 recommendations when guidelines were possible.

Key words: Burch urethropexy, midurethral sling, pubovaginal sling, stress urinary incontinence, single-incision sling

Cite this article as: Schimpf MO, Rahn DD, Wheeler TL, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;210:x.ex-x.ex.

From the Division of Gynecology and Urogynecology, Department of Obstetrics and Gynecology, University of Michigan Medical School, Ann Arbor, MI (Dr Schimpf); Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, TX (Dr Rahn); Department of Obstetrics and Gynecology, University of South Carolina School of Medicine Greenville, Greenville, SC (Dr Wheeler); Department of Obstetrics and Gynecology, Kaiser Permanente, Roseville, CA (Dr Patel); Department of Obstetrics and Gynecology, University of Texas Southwestern at Seton Healthcare Family, Austin, TX (Dr White); Department of Obstetrics and Gynecology and Reproductive Sciences, University of Texas Health Science Center at Houston, Houston, TX (Dr Orejuela); Division of Gynecologic Surgery, Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN (Dr El-Nashar); Division of Urogynecology, Department of Obstetrics and Gynecology, Kaiser Permanente, Oakland, CA (Dr Margulies); Division of Urogynecology, Department of Obstetrics and Gynecology, Carilion Clinic, Roanoke, VA (Dr Gleason); Department of Urogynecology, ProHealth Care, Women's Center, Medical College of Wisconsin, Waukesha, WI (Dr Aschkenazi); Icahn School of Medicine at Mount Sinai, Department of Obstetrics and Gynecology, New York, NY (Dr Mamik); Vanderbilt University Medical Center, Department of Obstetrics and Gynecology, Nashville, TN (Dr Ward); Tufts Medical Center, Institute for Clinical Research and Health Policy Studies, Boston, MA (Dr Balk); and Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology, Women and Infants Hospital of Rhode Island and Warren Alpert Medical School of Brown University, Providence, RI (Dr Sung).

Received Aug. 26, 2013; revised Nov. 22, 2013; accepted Jan. 21, 2014.

The Society of Gynecologic Surgeons provided funding for assistance by methods experts in systematic review and for logistic support.

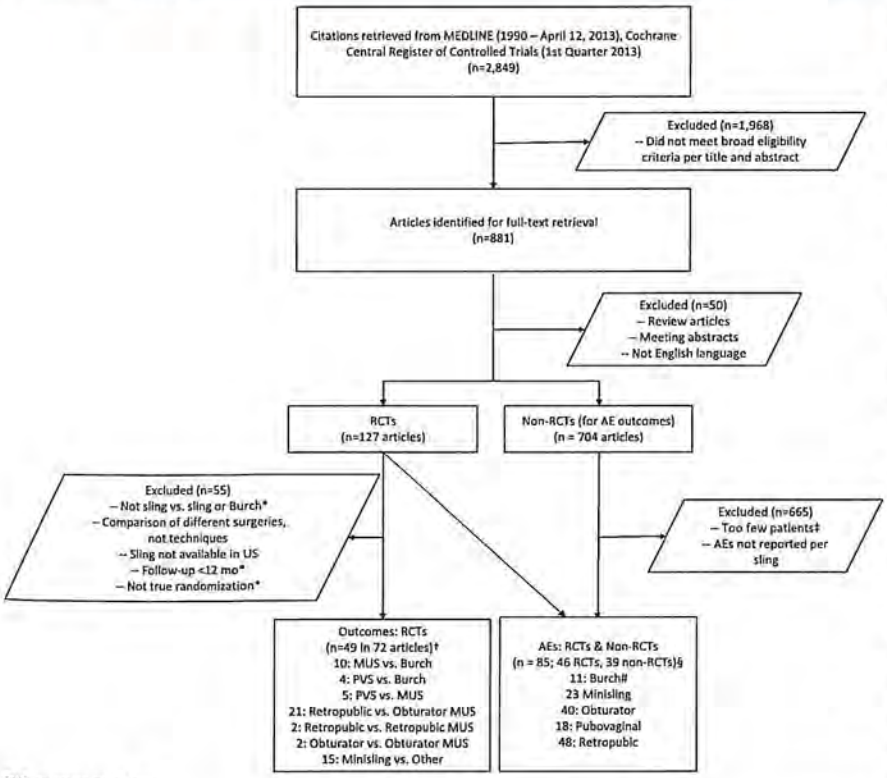
The authors report no conflict of interest.

Presented at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons, Charleston, SC, April 8-10, 2013.

Reprints: Megan O. Schimpf, MD, Obstetrics and Gynecology, Female Pelvic Medicine and Reconstructive Surgery, University of Michigan, L4000 Women's, 1500 E. Medical Center Dr., Ann Arbor, MI 48109. mschimpf@umich.edu.

0002-9378/$36.00 • http://dx.doi.org/10.1016/j.ajog.2014.01.030

FIGURE 1
Literature flow



PVS, pubovaginal slings.

*These studies were potentially eligible to be included for adverse event (AE) analyses; †Several studies had 3 arms and provided data for multiple comparisons; ‡For noncomparative studies, the following minimum sample size criteria were used: minisling obturator, n ≥120; minisling retropubic, n ≥100; obturator midurethral sling (MUS), n ≥1000; pubovaginal fascial, n ≥300; pubovaginal synthetic, n ≥120; retropubic MUS, n ≥1000; §Several studies reported on ≥2 slings; #Only from randomized controlled trials (RCTs).

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Stress urinary incontinence (SUI), or the involuntary loss of urine with activity such as coughing, laughing, and sneezing, is present in 15-80% of women.[1] Options for treating SUI include physical therapy, pessaries, urethral bulking injections, and surgery. Surgery traditionally consisted of Burch urethropexy or pubovaginal sling. Since 1996, when Ulmsten et al[2] published the initial paper about retropubic tension-free vaginal tape (TVT), the use of synthetic midurethral slings (MUS) has grown to become the most common surgery performed for SUI in women.[3] This type of surgery has evolved to also include options of obturator passage and smaller, single-incision synthetic slings (eg, "minislings").

The decision of which SUI procedure to perform can include suture-only, native tissue, mesh, laparoscopic, open incisions, small incisions, or single-incision surgery. Many studies have compared these options. The primary aim of our work was to utilize systematic review and meta-analysis methodology to compare objective and subjective cure rates in adult women with SUI between these different surgeries. The secondary outcomes were to compare surgical methods by quality-of-life measures, sexual function, and perioperative and adverse event (AE) data.

Materials and Methods

The Society of Gynecologic Surgeons Systematic Review Group includes members with clinical and surgical expertise on female SUI and in the conduct of systematic reviews and guideline development. This project was considered exempt from institutional review board approval.

Data sources and searches

We searched MEDLINE and Cochrane Central Register for Controlled Trials from Jan. 1, 1990 through April 12, 2013 (Figure 1). We excluded older studies because the TVT was not available in the United States prior to this. Search terms included "urinary incontinence," "urgency," "sling," "obturator," "retropubic," "pubovaginal," "vaginal tape," "urologic surgical procedures" (instrumentation or adverse effects), and related terms. The search was limited to comparative studies, cohort studies, and systematic reviews. The search was further limited to human and English-language studies. Meeting abstracts were excluded. Any review articles obtained in this search were excluded after reference lists were reviewed and articles not originally in the search were obtained. Study authors were not contacted.

Twelve reviewers independently double-screened the abstracts using the computerized screening program Abstrackr (Tufts Medical Center, Boston, MA).[4] To establish relevance and consensus among reviewers, all 12 screened and achieved consensus on an initial batch of 300 abstracts. Potentially relevant full-text articles were also independently double-screened by 12 reviewers.

Study selection

For the principal evaluation of outcomes, we included peer-reviewed randomized controlled trials (RCTs) with at least 12 months of follow-up (Table 1). Trials were excluded from outcomes analysis for poor randomization schemes, such as alternate assignment of patients or assignment based on day of the week or birth date. We included RCTs that compared ≥2 sling procedures or a sling procedure to Burch urethropexy performed in adult women for SUI. Studies that compared Burch urethropexy to any other surgery were excluded. Bulking injections were excluded because they are not similar enough to sling surgeries regarding cure, perioperative data, or AEs. When a study included 3 arms, it was analyzed as multiple 2-arm comparisons. For the evaluation of AEs we

TABLE 1
Randomized controlled trials included in systematic review

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
MUS vs Burch												
Bai et al,[9] 2005[a]	B	Retropubic MUS (TVT)	Burch	31	33	12 mo	X			X		
Bandarian et al,[10] 2011	C	Obturator MUS (TOT, unspecified)	Burch	31	31	25 mo mean		X	X	X		
Foote et al,[11] 2006	C	Retropubic MUS (SPARC)	Laparoscopic Burch	49	48	24 mo	X	X	X	X		
Liapis et al,[12] 2002	C	Retropubic MUS (TVT)	Burch	36	35	24 mo	X	X	X	X		
Paraiso et al,[13] 2004[b]	B	Retropubic MUS (TVT)	Laparoscopic Burch	36	36	21 mo	X	X	X	X	X	
Persson et al,[14] 2002	B	Retropubic MUS (TVT)	Laparoscopic Burch	38	33	12 mo	X	X	X	X		
Sivaslioglu et al,[15] 2007	A	Obturator MUS (Safyre T)	Burch	49	51	24 mo	X	X	X	X		
Téllez Martínez-Fornés et al,[16] 2009	B	Retropubic MUS (TVT)	Burch	24	25	36 mo	X	X	X	X	X	
Wang and Chen,[17] 2003	B	Retropubic MUS (TVT)	Burch	49	49	22 mo	X	X	X	X		
Ward et al,[18] 2002[c]	B	Retropubic MUS (TVT)	Burch	169	175	5 y	X		X	X	X	X
PVS vs Burch												
Albo et al,[19] 2007 (SISTEr Trial)[d]	A	PVS (autologous fascia)	Burch	326	329	24 mo	X	X	X	X	X	
Bai et al,[9] 2005[a]	B	PVS (autologous fascia)	Burch	28	33	12 mo	X			X		
Culligan et al,[20] 2003[e]	B	PVS (Gore-Tex)	Burch	17	19	73 mo	X		X	X		
Enzelsberger et al,[21] 1996	C	PVS (dura mater)	Burch	36	36	36 mo	X		X	X		
PVS vs MUS												
Amaro et al,[22] 2009	C	PVS (autologous fascia)	Retropubic MUS (TVT)	21	20	44 mo		X	X	X	X	
Bai et al,[9] 2005[a]	B	PVS (autologous fascia)	Retropubic MUS (TVT)	28	31	12 mo	X			X		
Guerrero et al,[23] 2010[f]	B	PVS (autologous fascia)	Retropubic MUS (TVT)	79	50	12 mo		X	X	X	X	
Sharifiaghdas and Mortazavi,[24] 2008	B	PVS (autologous fascia)	Retropubic MUS (TVT)	52	48	40 mo	X	X	X	X	X	
Tcherniakovsky et al,[25] 2009	C	PVS (autologous fascia)	Obturator MUS (Safyre T)	20	21	12 mo	X		X	X		
Retropubic vs obturator MUS												
Aniuliene,[26] 2009	C	TVT	TVT-O	114	150	12 mo		X	X	X		
Araco et al,[27] 2008	B	TVT	TVT-O	108	100	12 mo	X		X	X	X	
Ballester et al,[28] 2012[g]	B	Retropubic ISTOP	Transobturator ISTOP	42	46	48 mo	X	X	X	X	X	

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

(continued)

TABLE 1
Randomized controlled trials included in systematic review *(continued)*

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Barber et al,[29] 2008[h]	A	TVT	Monarc	88	82	18 mo	X	X	X	X	X	X
Deffieux et al,[30] 2010	A	TVT	TVT-O	75	74	24 mo	X	X	X	X	X	X
El-Hefnawy et al,[31] 2010	C	TVT	Obturator MUS (unspecified)	19	21	20 mo	X	X	X	X		
Freeman et al,[32] 2011	A	TVT	Monarc	93	100	12 mo		X	X	X	X	X
Karateke et al,[33] 2009	A	TVT	TVT-O	83	84	14 mo	X	X	X	X	X	
Krofta et al,[34] 2010	A	TVT	TVT-O	149	151	12 mo	X	X	X	X	X	X
Liapis et al,[35] 2006	C	TVT	TVT-O	46	43	12 mo	X	X	X	X		
Richter et al,[1] 2010 (TOMUS Trial)[i]	A	TVT	Obturator MUS (TVT-O or Monarc)	298	299	24 mo	X	X	X	X	X	X
Rinne et al,[36] 2008[j]	A	TVT	TVT-O	136	131	36 mo	X	X	X	X	X	
Ross et al,[37] 2009	B	Retropubic MUS (Advantage)	Obturator MUS (Obtryx)	105	94	12 mo	X	X	X	X	X	X
Scheiner et al,[38] 2012[k]	B	TVT	Monarc	80	40	12 mo	X	X	X	X	X	X
Scheiner et al,[38] 2012[k]	B	TVT	TVT-O	80	40	12 mo	X	X	X	X	X	X
Schierlitz et al,[39] 2008[l]	B	TVT	Monarc	82	82	36 mo	X	X	X	X		X
Teo et al,[40] 2011	B	TVT	TVT-O	66	61	12 mo	X	X	X	X	X	
Wang F et al,[41] 2010	A	TVT	Obturator MUS (out-to-in)	70	70	12 mo	X	X	X	X	X	
Wang W et al,[42] 2009	B	TVT	TVT-O	160	155	36 mo	X		X	X		
Wang YJ et al,[43] 2011[m]	B	TVT	TVT-O	32	36	12 mo	X		X	X		
Zullo et al,[44] 2007[n]	B	TVT	TVT-O	35	37	5 y	X	X	X	X	X	X
Retropubic MUS vs retropubic MUS												
Andonian et al,[45] 2005	B	SPARC	TVT	41	43	12 mo	X	X	X	X		
Tseng et al,[46] 2005	B	SPARC	TVT	31	31	24 mo	X		X	X		
Obturator MUS vs obturator MUS												
Abdel-Fattah et al,[47] 2010 (E-TOT Trial)[o]	B	ARIS TOT (out-to-in)	TVT-O (in-to-out)	171	170	12 mo	X	X		X	X	X
Scheiner et al,[38] 2012[k]	B	Monarc	TVT-O	40	40	12 mo	X	X	X	X	X	

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

(continued)

TABLE 1
Randomized controlled trials included in systematic review *(continued)*

Study	Study quality[r]	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Minisling vs any other sling												
Andrada Hamer et al,[48] 2013	B	TVT-Secur H	TVT	64	69	12 mo	X	X	X	X		
Barber et al,[49] 2012	A	TVT-Secur U	TVT	136	127	12 mo	X	X	X	X	X	X
Hinoul et al,[50] 2011	A	TVT-Secur H	TVT-O	97	98	12 mo	X	X	X	X	X	
Hota et al,[51] 2012	A	TVT-O	TVT-Secur	44	42	12 mo	X	X	X	X	X	
Kim et al,[52] 2010	B	TVT-Secur U	TVT-Secur H	53	62	12 mo	X	X	X	X	X	X
Lee et al,[53] 2010	A	TVT-Secur U	TVT-Secur H	165	165	12 mo	X	X	X	X	X	X
Masata et al,[54] 2012[p]	A	TVT-Secur U	TVT-O	65	68	24 mo	X	X	X	X	X	
Masata et al,[54] 2012[p]	A	TVT-Secur H	TVT-O	64	68	24 mo	X	X	X	X	X	
Masata et al,[54] 2012[p]	A	TVT-Secur U	TVT-Secur H	65	64	24 mo	X	X	X	X	X	
Oliveira et al,[55] 2011[q]	C	TVT-Secur H	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al,[55] 2011[q]	C	MiniArc	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al,[55] 2011[q]	C	TVT-Secur H	MiniArc	30	30	12 mo	X		X	X		
Tommaselli et al,[56] 2010	B	TVT-Secur H	TVT-O	42	42	12 mo	X		X	X	X	
Wang YJ et al,[43] 2011[m]	B	TVT-Secur	TVT	34	32	12 mo	X		X	X		
Wang YJ et al,[43] 2011[m]	B	TVT-Secur	TVT-O	34	36	12 mo	X		X	X		

Advantage; Boston Scientific Corp., Natick, MA; Gore-Tex; Gore Medical, Flagstaff, AZ; ISTOP, CL Medical, Winchester, MA; MiniArc; AMS, Minnetonka, MN; Monarc; AMS; Obtryx; Boston Scientific Corp.; Safyre; Promedon, Cordoba, Argentina; SPARC; AMS; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur, Ethicon Gynecare.

AE, adverse event; *MUS*, midurethral sling; *OC*, objective cure; *Po*, perioperative outcomes; *PVS*, pubovaginal sling; *QoL*, Life-of-life outcomes; *SC*, subjective cure; *SF*, sexual function outcomes; *TOMUS*, Trial of Midurethral Slings; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

[a] 3-Arm trial comparing PVS (autologous fascia) vs TVT vs Burch; [b] Jelovsek et al[59] 2008; [c] Ward et al[60] 2004 and Ward et al[61] 2008; [d] Tennstedt et al[62] 2005, Tennstedt et al[63] 2008, Chai et al[64] 2009, Kraus et al[65] 2011, Brubaker et al[66] 2012; [e] Sand et al[67] 2000; [f] Trial also included PVS (Pelvichol) arm (n = 72) that was not included as Pelvichol is off market; [g] Daraï et al[68] 2007 and David-Montefiore et al[69] 2006; [h] Barber et al[70] 2008; [i] Albo[71] 2008, Brubaker et al[72] 2011, Zyczynski et al[73] 2012, Albo et al[3] 2012; [j] Laurikainen et al[74] 2007 and Palva et al[75] 2010; [k] 3-Arm trial comparing Monarc vs TVT vs TVT-O; [l] Schierlitz et al[76] 2012 and De Souza et al[77] 2012; [m] 3-Arm trial comparing TVT-Secur vs TVT vs TVT-O; [n] Angioli et al[78] 2010; [o] Abdel-Fattah et al[79] 2010 and Abdel-Fattah et al[80] 2012; [p] 3-Arm trial comparing TVT-Secur H vs TVT-Secur U vs TVT-O; [q] 3-Arm trial comparing TVT-O vs TVT-Secur H vs MiniArc; [r] A (good), B (fair), C (poor).

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

TABLE 2
Categorization of outcomes analyzed from randomized controlled trials

Outcome category of interest	Specific outcomes collected
Objective cure	Cough stress test
	Pad testing
	Urodynamic stress incontinence
	Voiding diary data
Subjective cure	Sandvik Incontinence Severity Index
	International Consultation on Incontinence Questionnaire (ICIQ)
	Patient Global Impression of Improvement (PGI-I)
	Pelvic Floor Distress Inventory (PFDI)
	Urinary Distress Inventory (UDI)
	Bristol female lower urinary tract symptom (BFLUTS)
	Measures such as "better" or "satisfied"
	"Would recommend to a friend"
	Met expectations
Perioperative outcomes	Estimated blood loss, time to return to normal activity/work, operative time, hospital time, length of stay, length of use of catheter, pain
Quality of life or satisfaction	Kings Health Questionnaire (KHQ)
	Measures of activities of daily living
	Urinary Incontinence Quality-of-life Scale (I-QOL)
	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Floor Impact Questionnaire/Incontinence Impact Questionnaire (PFIQ/IIQ)
	International Consultation on Incontinence Questionnaire (ICIQ)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
Sexual function	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
	Dyspareunia
	"Return to normal sex life"
Adverse events	Table 3

IUGA, International Urogynecology Association.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

also included trials excluded from RCT analysis, nonrandomized comparative studies, and cohort (pre-post) studies of any follow-up duration. Because of the volume of these studies, sample size limitations were placed to restrict the number of studies to only those with the most patients and therefore highest potential for identifying a complication (Figure 1). Studies included for AEs had to evaluate at least 1 sling type, and information about any other comparator surgery was not collected. Sling types of interest included MUS (retropubic, obturator), pubovaginal slings at the bladder neck (biologic, synthetic, or autologous), and minislings. All studies had to report results for cohorts (or study arms) of women who all received the same sling type (or Burch urethropexy); studies that combined women who received different sling types in their analyses were excluded. Studies that examined various aspects of surgical technique, anesthesia, or surgeon training were excluded if the same type of sling was used in each arm. Data were excluded if the surgical product used was not available in the United States as of April 2013.

Outcomes of interest from RCTs fell into 6 categories: objective cure, subjective cure, perioperative outcomes, quality of life or satisfaction, sexual function, and AEs (Table 2). Studies with nonrandomized designs were included only for AEs. Information on cost was not collected.

Data extraction and quality assessment

Data were extracted by 1 of 12 reviewers using a standard data extraction form and confirmed by another; discrepancies were resolved by consensus. We extracted data on study characteristics, participant characteristics, funding source, details on the interventions, length of follow-up, outcomes of interest measured, and how these outcomes were assessed. After data extraction, the lead reviewer and methodologist categorized all outcomes extracted from the RCTs into the 6 outcome categories listed above. Two reviewers also categorized all AEs into 22 categories as listed in Table 3. The underlying data, together with additional extracted information, are accessible online at http://srdr.ahrq.gov/ in the project Sling surgery for stress urinary incontinence in women: Society of Gynecologic Surgeons 2013.

We assessed the methodological quality of each RCT using predefined criteria from a 3-category system modified from the Agency for Healthcare Research and Quality.[5] Studies were graded as good (A), fair (B), or poor (C)

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117]

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Estimated blood loss >200 mL					
Obturator	4	0.22% (0.03–1.59%)	1	448	0.00–1.79%
Minisling	3	1.1% (0.5–1.9%)	10	888	0.00–3.68%
Retropubic	4	1.5% (1.0–2.1%)	33	2071	0.21–4.76%
Transfusion					
Burch	3	0.00% (0.00–7.73%)	0	105	0.00–0.00%
Obturator	6	0.17% (0.02–1.22%)	1	584	0.00–0.40%
Retropubic	13	0.40% (0.28–0.55%)	31	8105	0.00–4.00%
Minisling	5	0.51% (0.23–1.14%)	6	1177	0.00–0.74%
Pubovaginal	5	1.9% (0.9–3.2%)	10	515	0.00–5.17%
Hematoma					
Obturator	18	0.59% (0.35–0.89%)	17	2995	0.00–2.41%
Retropubic	25	0.88% (0.74–1.0%)	184	15,950	0.00–16.13%
Minisling	2	0.85% (0.21–3.44%)	2	236	0.74–1.00%
Burch	4	1.4% (0.6–2.6%)	8	542	0.00–5.71%
Pubovaginal	5	2.2% (1.2–3.4%)	14	677	0.00–5.17%
Dyspareunia					
Retropubic	2	0.00% (0.01–1.64%)	0	488	0.00–0.00%
Obturator	6	0.16% (0.02–1.14%)	1	624	0.00–0.40%
Minisling	11	0.74% (0.40–1.2%)	19	1809	0.00–6.49%
Pubovaginal	5	0.99% (0.39–1.9%)	8	696	0.00–2.63%
Return to operating room for erosion					
Burch	2	0.28% (0.04–2.03%)	1	352	0.00–0.30%
Minisling	3	1.4% (0.5–2.8%)	5	399	0.53–2.86%
Pubovaginal	5	1.6% (0.8–2.7%)	16	640	0.00–12.50%
Retropubic	12	1.9% (1.0–3.0%)	13	703	0.00–6.45%
Obturator	7	2.7% (1.5–4.3%)	14	518	0.00–8.24%
Exposure					
Burch	4	0.00% (0.02–6.22%)	0	130	0.00–0.00%
Retropubic	29	1.4% (1.1–1.7%)	84	5684	0.00–12.90%
Minisling	19	2.0% (1.5–2.6%)	61	2408	0.00–19.05%
Obturator	31	2.2% (1.7–2.7%)	66	3253	0.00–10.00%
Pubovaginal	10	5.4% (4.0–7.0%)	48	851	0.00–15.52%
Wound infection					
Minisling	3	0.31% (0.05–0.80%)	2	852	0.00–1.04%
Obturator	14	0.74% (0.43–1.1%)	14	2348	0.00–2.11%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

(continued)

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Retropubic	13	0.75% (0.54–0.98%)	43	5781	0.00–13.04%
Pubovaginal	3	2.6% (0.8–5.4%)	4	174	0.85–5.56%
Burch	5	7.0% (4.3–10%)	17	269	3.13–9.68%
Urinary tract infection					
Minisling	13	3.6% (2.8–4.6%)	72	1762	0.74–18.33%
Pubovaginal	4	4.2% (2.5–6.3%)	21	420	1.84–18.75%
Obturator	21	4.3% (3.4–5.2%)	88	1826	0.00–16.79%
Burch	7	5.9% (4.2–7.9%)	55	648	0.00–31.51%
Retropubic	21	11.0% (9.7–11%)	718	6286	0.00–23.33%
Bowel injury					
Obturator	5	0.00% (0.00–1.96%)	0	410	0.00–0.00%
Retropubic	7	0.34% (0.09–1.36%)	2	594	0.00–1.57%
Minisling	1	0.74% (0.10–5.30%)	1	136	0.74–0.74%
Burch	1	3.13% (0.44–23.63%)	1	32	3.13–3.13%
Nerve injury					
Minisling	1	0.00% (0.02–5.95%)	0	136	0.00–0.00%
Retropubic	4	0.06% (0.01–0.43%)	1	1642	0.00–0.07%
Obturator	3	0.61% (0.09–4.36%)	1	165	0.00–1.72%
Ureteral injury					
Retropubic	1	0.00% (0.00–9.25%)	0	88	0.00–0.00%
Pubovaginal	4	0.18% (0.03–1.26%)	1	567	0.00–1.28%
Burch	1	0.61% (0.15–2.46%)	2	329	0.61–0.61%
Obturator	1	1.22% (0.17–8.87%)	1	82	1.22–1.22%
Vascular injury					
Obturator	2	0.00% (0.00–6.75%)	0	120	0.00–0.00%
Retropubic	4	0.08% (0.04–0.18%)	6	7149	0.00–0.09%
Overactive bladder/urgency					
Burch	3	4.3% (2.5–6.5%)	17	387	2.86–21.74%
Obturator	8	5.3% (4.2–6.5%)	106	1485	0.00–34.53%
Minisling	11	5.4% (4.4–6.5%)	103	1769	2.22–21.00%
Retropubic	15	6.9% (6.0–7.7%)	374	3486	0.76–45.00%
Pubovaginal	5	8.6% (6.5–11%)	55	558	3.37–38.10%
Retention lasting <6 wk postoperatively					
Minisling	13	2.1% (1.5–2.8%)	36	1778	0.00–5.88%
Obturator	17	2.3% (1.8–3.0%)	70	2629	0.00–10.00%
Retropubic	18	3.1% (2.7–3.5%)	248	7127	0.00–21.74%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Pubovaginal	10	12% (10.2–14%)	158	1053	3.03–81.97%
Burch	5	17% (13–21%)	55	288	0.00–32.88%
Retention lasting >6 wk postoperatively					
Obturator	6	2.4% (1.4–3.6%)	70	2629	0.00–10.00%
Retropubic	9	2.7% (2.1–3.4%)	248	7127	0.00–21.74%
Minisling	2	3.3% (1.6–5.7%)	36	1778	0.00–5.88%
Pubovaginal	6	7.5% (5.4–10%)	158	1053	3.03–81.97%
Burch	4	7.6% (4.7–11%)	55	288	0.00–32.88%
Return to operating room for urinary retention					
Burch	4	0.00% (0.00–1.54%)	0	522	0.00–0.00%
Obturator	22	1.1% (0.7–1.5%)	23	2342	0.00–6.67%
Retropubic	21	1.2% (0.9–1.7%)	48	3103	0.00–24.00%
Minisling	12	1.9% (1.2–2.9%)	16	970	0.00–5.00%
Pubovaginal	15	3.0% (2.3–3.9%)	57	1667	0.00–7.69%
Groin pain					
Pubovaginal	2	0.34% (0.09–1.36%)	2	591	0.00–0.61%
Minisling	12	0.62% (0.30–1.1%)	14	1619	0.00–5.26%
Burch	2	1.10% (0.42–2.98%)	4	364	0.00–11.43%
Retropubic	12	1.5% (1.0–2.1%)	29	1811	0.00–5.56%
Obturator	17	6.5% (5.3–7.7%)	128	1594	0.00–36.67%
Leg pain					
Retropubic	4	0.62% (0.16–2.51%)	2	322	0.00–1.69%
Minisling	4	1.6% (0.5–3.2%)	4	337	0.00–2.63%
Obturator	7	16% (13–19%)	112	649	3.66–60.87%
Bladder perforation					
Obturator	32	0.70% (0.46–0.98%)	22	4000	0.00–4.76%
Minisling	6	0.85% (0.40–1.5%)	12	1138	0.00–4.41%
Pubovaginal	14	2.3% (1.5–3.3%)	23	1069	0.00–5.56%
Burch	10	2.8% (1.7–4.1%)	19	753	0.00–6.25%
Retropubic	41	3.6% (3.3–3.9%)	420	11,390	0.00–24.39%
Urethral perforation					
Burch	1	0.00% (0.00–34.04%)	0	25	0.00–0.00%
Obturator	7	0.20% (0.05–0.80%)	2	1013	0.00–1.72%
Retropubic	8	0.41% (0.19–0.72%)	17	2211	0.00–5.37%
Minisling	1	2.70% (0.38–20.26%)	1	37	2.70–2.70%

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Vaginal perforation					
Pubovaginal	1	0.00% (0.00–2.46%)	0	326	0.00–0.00%
Burch	2	0.21% (0.03–1.50%)	1	475	0.00–0.30%
Retropubic	12	0.73% (0.40–1.2%)	19	1892	0.00–15.00%
Minisling	10	1.3% (0.8–1.9%)	20	1538	0.00–4.84%
Obturator	20	2.8% (2.2–3.5%)	82	2498	0.00–10.87%
Deep vein thrombosis					
Obturator	2	0.00% (0.00–12.03%)	0	68	0.00–0.00%
Retropubic	3	0.06% (0.01–0.43%)	1	1660	0.00–0.07%
Pubovaginal	4	0.35% (0.09–1.42%)	2	567	0.00–1.28%
Burch	3	0.58% (0.11–1.4%)	4	506	0.00–3.23%

AE, adverse event; *CI*, confidence interval.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

quality based on the likelihood of biases and completeness of reporting. Grades for different outcomes could vary within the same study.

Data synthesis and analysis

We were able to identify comparisons for MUS vs Burch, pubovaginal slings vs Burch, pubovaginal slings vs MUS, retropubic MUS vs obturator MUS, retropubic MUS vs retropubic MUS (based on route of passage), obturator MUS vs obturator MUS (based on route of passage), and minisling vs other sling. When at least 3 RCTs compared the same surgeries for the same outcomes and provided adequate data for metaanalysis (including for AEs), we performed random effects model metaanalyses to estimate pooled odds ratios (ORs). We included data from the time point closest to 12 months' follow-up that were reported. For objective cure, studies used cough stress test, pad test, or both methods. Across studies, we treated the different methods as equivalent (ie, we included both methods in the metaanalyses), but when a single study reported both methods, we preferentially chose stress test over pad test or a combined outcome (both pad and stress tests). When at least 3 studies (pre-post, nonrandomized comparative, or RCT) reported the same AE for the same sling type, we performed random effects model metaanalyses of the arcsine transformed proportion of women with the outcome.[6] The arcsine transformed proportion was used to minimize bias due to the nonnormal distribution when proportions are close to 0. However, when the total number of events was <3 or metaanalysis gave an implausible summary estimate, the exact proportion and confidence interval (CI) were calculated for the total number of events and women at risk.[7] These absolute rates of AEs are compared qualitatively between procedures, and all data are presented in Table 3.

For each comparison of different sling types (or vs Burch), we generated an evidence profile by grading the quality of evidence for each outcome according to the Grades for Recommendation, Assessment, Development, and Evaluation system. The process considered the methodological quality, consistency of results across studies, directness of the evidence, and imprecision or sparseness of evidence to determine an overall quality of evidence. Four quality rating categories were possible: high (A), moderate (B), low (C), and very low/insufficient (D).[8] Evidence profiles for the reviewed studies are in the Appendix.

We developed clinical practice guideline statements incorporating the balance between benefits and harms of the compared interventions when the data were sufficient to support these statements. Each guideline statement was assigned an overall level of strength of the recommendation (1 = strong, 2 = weak) based on the quality of the supporting evidence and the size of the net benefit. The strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm. The wording and its implications for patients, physicians, and policymakers are detailed in Table 4.

We presented our findings at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons in April 2013 in Charleston, SC. A link to the guidelines and manuscript was then e-mailed to the entire membership for review and vetting in August 2013 prior to submission for publication.

RESULTS

The MEDLINE search identified 2849 abstracts, of which we retrieved 881

TABLE 4
Society for Gynecologic Surgeons Systematic Review Group sling surgery for stress urinary incontinence in women, clinical practice guidelines

Midurethral sling vs Burch (open or laparoscopic)

For women considering midurethral slings or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure and that decision be based on: (1) which adverse events are of greatest concern to patient; and (2) any other planned concomitant surgeries (vaginal vs abdominal route). (1A)
- Midurethral slings may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas. (1C)
- Burch procedures may result in lower rates of return to operating room for retention, erosion, overactive bladder symptoms, and groin pain. (1C)

Pubovaginal sling vs Burch

For women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes. (1A)
- Burch procedure results in lower rates of erosion, overactive bladder symptoms, and retention requiring reoperation. (1C)
- Pubovaginal slings result in lower rates of wound infection, bladder/vaginal perforation, and bowel injury. (1C)

Pubovaginal sling (biologic and synthetic) vs midurethral sling (only TVT was studied)

For women considering pubovaginal or midurethral sling for treatment of SUI, we recommend midurethral sling for better subjective cure outcomes. (2C)
- Midurethral slings may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay. (2D)
- Pubovaginal slings may result in lower rates of adverse events such as urinary tract infection and vaginal perforation. (2D)

Retropubic vs obturator midurethral slings

For women considering retropubic or transobturator midurethral sling, we recommend either intervention for objective and subjective cure and that decision be based on which adverse events are of greatest concern to patient. (1A)
- Retropubic slings result in lower rates of sling erosion, need to return to operating room for treatment of sling erosion, groin/leg pain, and vaginal perforation. (1D)
- Transobturator midurethral slings result in shorter operative time, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less overactive bladder symptoms. (1D)

Obturator vs obturator or retropubic vs retropubic midurethral slings

There is insufficient evidence to provide recommendation for choosing among specific obturator or retropubic slings.

Minisling (TVT-Secur U/H position and MiniArc studied) vs other sling (TVT and TVT-O studied)

For women considering minislings (specifically TVT-Secur in H or U configuration) compared to traditional midurethral slings for treatment of SUI, we recommend traditional midurethral sling to maximize cure rates. (1A)
- Route of traditional midurethral sling that would be performed is important consideration in regard to adverse events compared with minislings. For example, minislings have similar rates of postoperative overactive bladder symptoms compared with obturator slings, but lower rates compared with retropubic slings. Exposure of sling postoperatively is similar between obturator slings and minislings, but retropubic slings have lower rates than both other types. (1D)
- Dyspareunia is more common with minisling than either retropubic or obturator sling, but absolute rates are low for all types of slings. (1D)

MiniArc; AMS, Minnetonka, MN; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur; Ethicon Gynecare.

SUI, stress urinary incontinence; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

full-text papers that were further assessed in detail (Figure 1). This process resulted in 127 papers detailing RCTs (Table 1), from which there were 49 unique, eligible trials. There were also 704 additional papers reflecting other study designs, which were considered for AE data (Table 3). After limiting the non-RCT papers to those with the largest number of patients, we included 39 of those studies in addition to collecting AE information from RCTs (Table 3).

We categorized the trials into 6 comparisons, which are discussed in detail below and in Table 1.

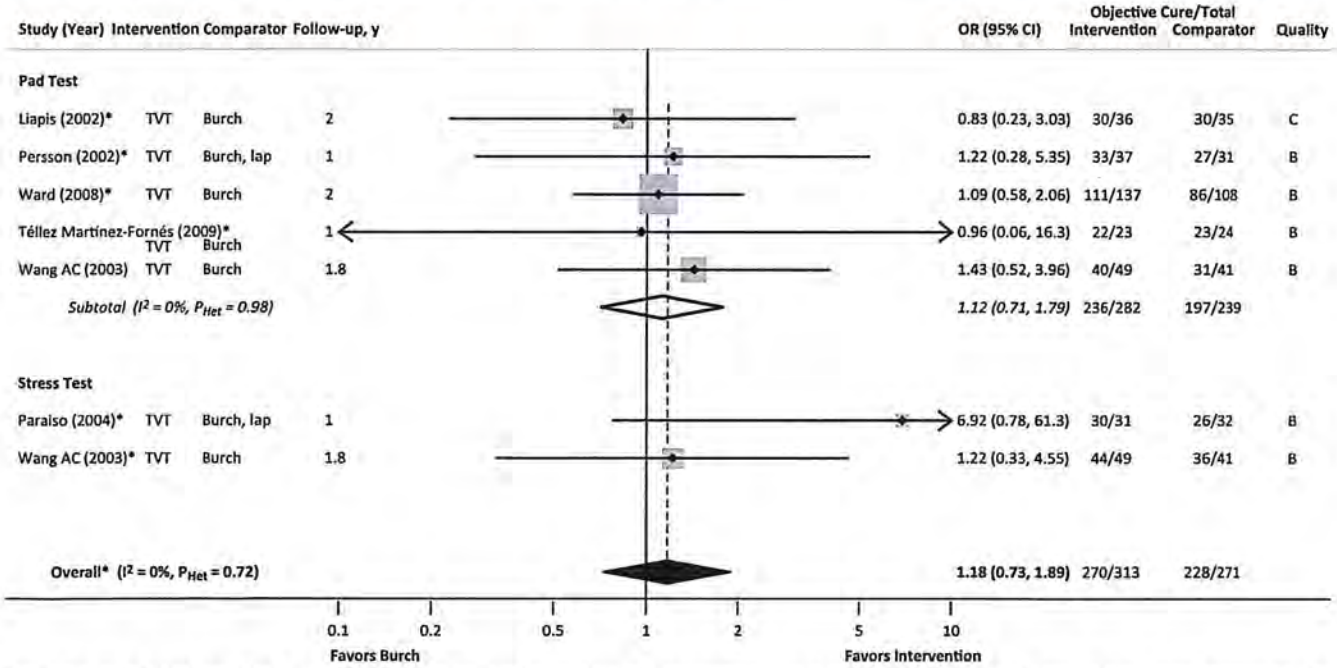
MUS vs Burch urethropexy

There were 10 RCTs for this comparison with overall moderate quality of evidence (Supplementary Table 1).[9-18] Two studies examined obturator MUS,[10,15] while the remaining analyzed a retropubic sling vs Burch urethropexy, which was performed via laparotomy except in 3 studies that analyzed laparoscopic Burch surgery.[11,13,14] There were no studies comparing minislings to Burch urethropexy.

The evidence reviewed did not support a difference between the 2 surgeries with regard to objective cure, subjective cure, quality-of-life, or sexual function outcomes. While 8 studies provided data about cure outcomes, there were fewer studies evaluating quality of life[13,16,18] and sexual function.[18]

Metaanalysis of objective cure did not show a significant difference for sling

FIGURE 2
Metaanalysis for objective cure: MUS vs Burch urethropexy



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *MUS*, midurethral slings; *OR*, odds ratio; P_{Heh} χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

compared to Burch (OR, 1.18; 95% CI, 0.73–1.89) (Figure 2). The 6 RCTs that met inclusion for this outcome analyzed TVT vs Burch, which was performed open or laparoscopically.

For subjective cure, the metaanalysis included retropubic slings (all TVT) and obturator slings (unspecified obturator sling or Safyre T; Promedon, Cordoba, Argentina) (Figure 3). The pooled OR for all analyses showed no significant difference but favored slings compared to Burch (OR, 1.12; 95% CI, 0.79–1.60). Similar results were seen for metaanalyses of retropubic and obturator slings compared individually to the Burch procedure (Figure 3).

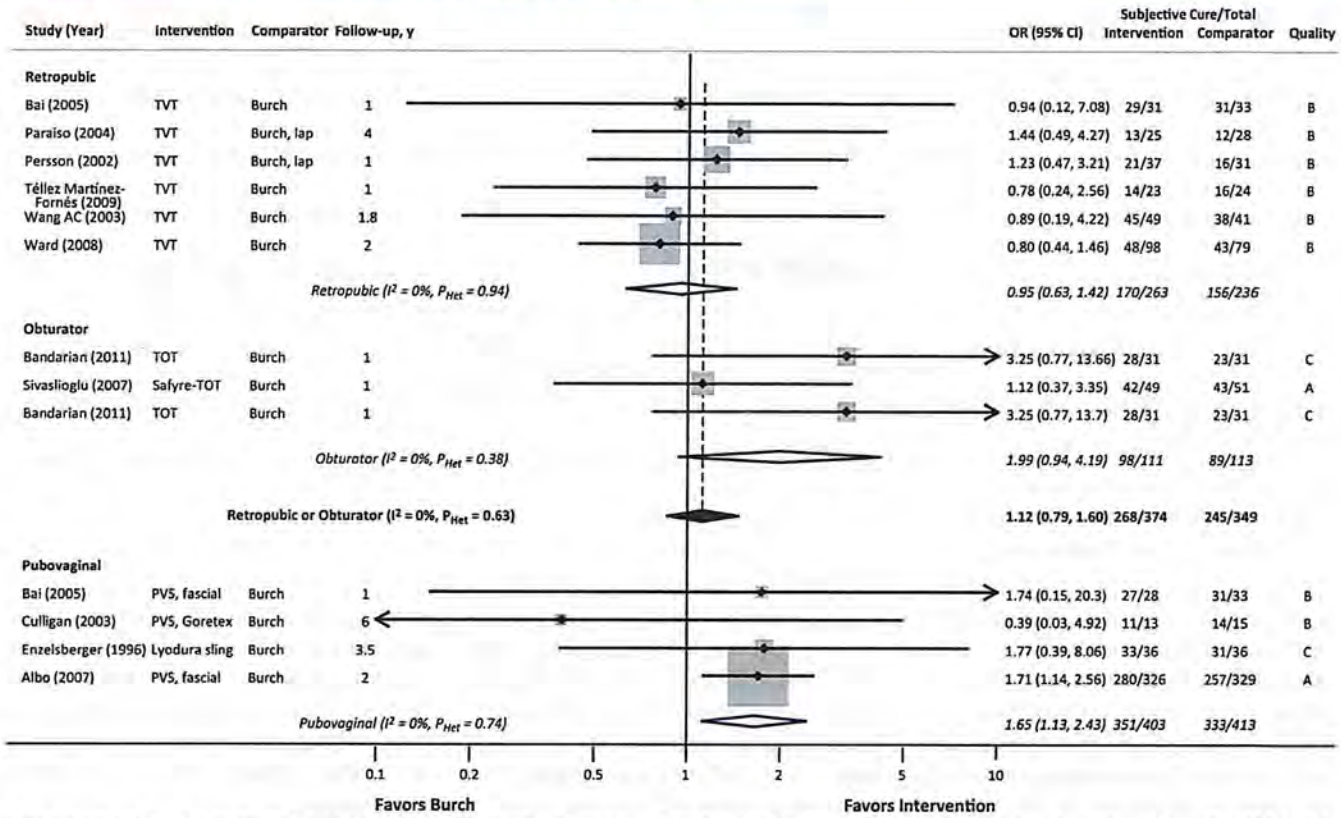
Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Analysis of perioperative and AE data for the absolute rates of complications per type of surgery showed that MUS may result in lower rates of perioperative AEs such as postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas (Appendix and Table 3). Burch procedures may result in lower rates of longer-term AEs such as return to the operating room for retention or erosion, overactive bladder (OAB) symptoms, and groin pain (Table 3). Metaanalysis of AE outcomes that were similar across studies showed no significant difference among these procedures for postoperative OAB symptoms, return to the operating room for erosion, and return to the operating room for retention. Interpretation of these rates is also dependent on the route of the MUS (obturator vs retropubic) that would be chosen, although more studies were available using retropubic slings for this comparison, weighting our analysis.

In summary, for women considering MUS or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure, with the decision based on AEs and other planned concomitant surgeries (vaginal vs abdominal route) (Table 4).

Pubovaginal slings vs Burch urethropexy

There were 4 RCTs for this comparison with an overall high quality of evidence (Supplementary Table 2).[9,19-21] The pubovaginal slings in these studies were composed of autologous fascia, Gore-Tex (Gore Medical, Flagstaff, AZ), or human dura mater.[9,19-21] The data for this grouping included the SISTEr trial, a high-quality, multicenter network trial with 655 subjects investigating autologous pubovaginal slings compared to Burch surgery (Table 1).[19] No studies reported sexual function data and only 1 reported quality-of-life outcomes.[19] The evidence favored sling procedures compared to Burch for subjective and objective cure outcomes.

FIGURE 3
Metaanalysis for subjective cure: slings vs Burch urethropexy



Forest plots subdivided by slings being compared with Burch urethropexy. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

There was an inadequate number of studies to support a metaanalysis of objective cure. Subjective cure outcome metaanalysis favored pubovaginal sling compared to Burch (OR, 1.65; 95% CI, 1.13–2.43) (Figure 3).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Looking at absolute rates of AEs per procedure, a Burch procedure results in lower rates of OAB symptoms, transfusion, hematomas, and return to the operating room for retention or erosion. Pubovaginal slings result in lower rates of wound infection, groin pain, urinary tract infection, and bladder/vaginal perforation. Metaanalysis of AE information showed no significant difference between the 2 surgeries for postoperative OAB symptoms and return to the operating room for erosion. There was a greater risk of return to the operating room for retention with the pubovaginal sling in the 2 studies that could be combined for this question (OR, 14.9; 95% CI, 1.35–165.15; $P = .028$).

In summary, for women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes (Table 4).

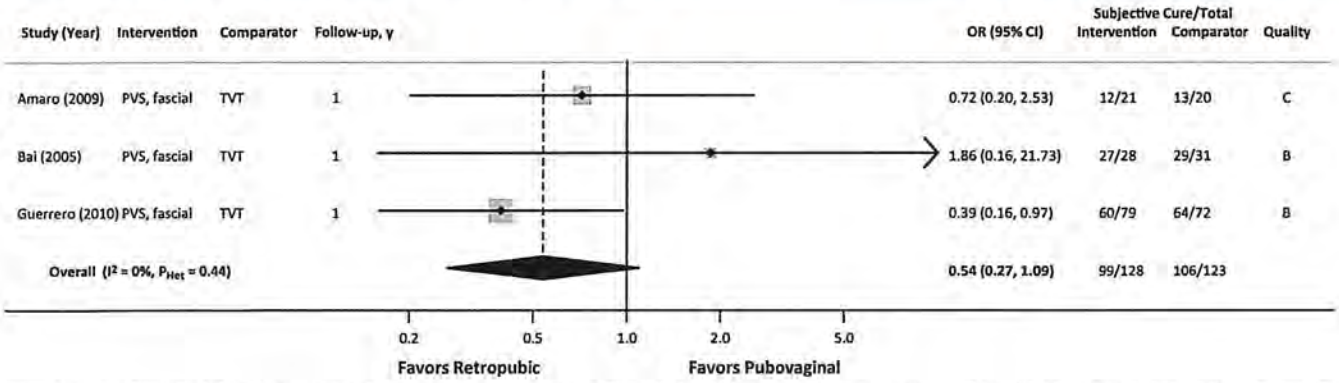
Pubovaginal slings vs MUS

There were 5 RCTs for this grouping and the evidence was overall of low quality (Supplementary Table 3).[9,22-25] The only MUS included in these studies was a retropubic TVT sling. There are no RCTs comparing pubovaginal slings to obturator MUS or minislings. No studies reported sexual function data. Review of the available data did not support a difference between procedures for either cure outcome.

Metaanalysis of data for subjective cure outcomes favors placement of MUS compared to pubovaginal slings (OR, 0.40; 95% CI, 0.18–0.85) (Figure 4). There were inadequate studies to support a metaanalysis for objective cure. Metaanalysis for the satisfaction outcome was also not possible due to a limited number of studies.

Comparing absolute complication rates for the surgeries in general, MUS resulted in lower rates of operating room time, blood loss, transfusion, wound infection, retention, OAB symptoms, and hospital stay (Appendix and Table 3). Interpretation of these rates is also dependent on the route of MUS (obturator vs retropubic) that would be chosen. Pubovaginal slings result in

FIGURE 4
Metaanalysis for subjective cure: pubovaginal vs MUS



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

lower rates of urinary tract infection and vaginal perforation than either route of MUS (Table 3). Metaanalysis of AE information showed no significant difference between these surgeries for postoperative OAB symptoms, return to the operating room for retention, or return to the operating room for erosion.

Driven by the metaanalysis information, for women considering a pubovaginal sling or MUS for treatment of SUI, we recommend MUS for better subjective cure (Table 4).

Retropubic MUS vs obturator MUS

This comparison had the most studies with 21 RCTs with large numbers of patients enrolled (Supplementary Table 4).[1,26-44] The quality of evidence was high, including Trial of Midurethral Slings (TOMUS), a high-quality multicenter network trial with 597 participants.[1] The evidence did not show a difference for objective or subjective cure outcomes between the 2 slings. Quality-of-life and sexual function outcomes were also similar between the 2 procedures.

Metaanalysis of objective cure data favored retropubic slings but was not significant (OR, 1.18; 95% CI, 0.95–1.47) (Figure 5). The retropubic sling studied was a TVT in all studies in the metaanalysis.

Similarly, for subjective cure, metaanalysis favored retropubic slings (OR, 1.17; 95% CI, 0.91–1.51) but was not significant (Figure 6). Again, the retropubic sling for included studies was always a TVT while the obturator slings included a variety of slings and routes of passages.

Four studies were included in a metaanalysis of satisfaction outcomes (Figure 7), which favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52–1.13).

AE and perioperative outcome data were highly variable by each outcome and did not provide a consistent direction when examined by absolute rates of complications for each surgery (Appendix and Table 3). Retropubic slings result in lower absolute rates of sling erosion, need to return to the operating room for treatment of sling erosion, nerve injury, ureteral injury, groin/leg pain, and vaginal perforation. Obturator MUS result in shorter operative time, lower blood loss, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less OAB symptoms. Metaanalysis showed that postoperative OAB symptoms were more common in patients following retropubic slings (OR, 1.41; 95% CI, 1.01–1.98, $P = .046$). There was no difference between slings on metaanalysis of return for operating room for erosion or for retention. There were too few studies that examined subpopulations of stress-incontinent patients (eg, those with intrinsic sphincter deficiency or prior surgical failures) to allow metaanalysis.

In summary, for women considering a retropubic or transobturator MUS, we recommend either intervention for objective and subjective cure; the decision should be based on surgeon expertise accounting for AEs (Table 4).

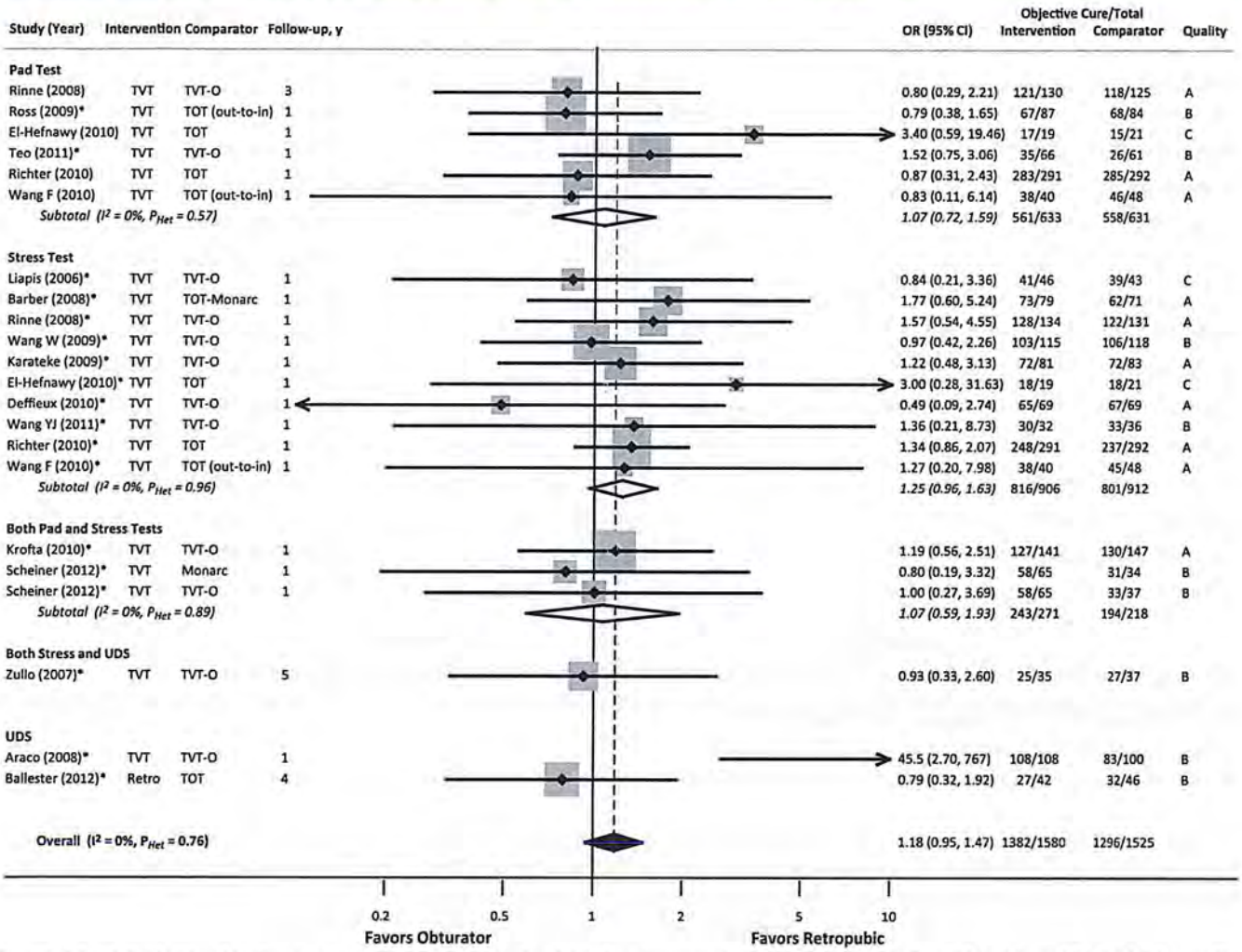
Retropubic MUS vs retropubic MUS

There was a limited number (2) of RCTs for this question, and moderate-quality evidence (Table 1) (Supplementary Table 5).[45,46] These studies each compared top-down passage (SPARC; AMS, Minnetonka, MN) to bottom-up passage (TVT). The evidence does not support a difference in outcomes between the retropubic slings studied. No studies reported quality-of-life or sexual function data.

Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

FIGURE 5
Metaanalysis for objective cure: retropubic (retro) vs obturator midurethral slings



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator; *UDS*, urodynamic study.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Obturator MUS vs obturator MUS

There have been 2 RCTs investigating this question, which provided low-quality evidence (Table 1) (Supplementary Table 6).[39,47] The evidence does not support a difference in outcomes between the routes of obturator slings studied.

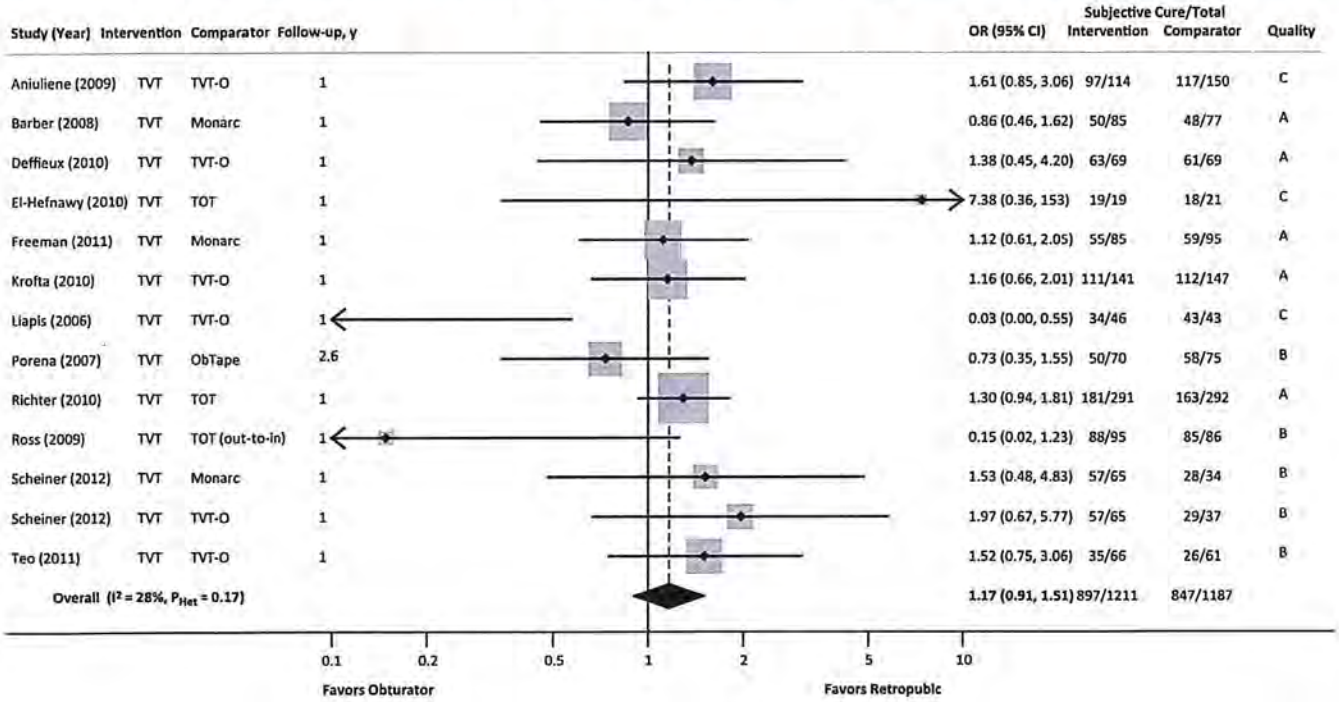
Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

Minislings vs any other slings

There were 15 RCTs providing data for this question, which represented 3-arm or 2-arm studies by original design (Table 1) (Supplementary Table 7).[43,48-56] The comparator arm of traditional full-length MUS was either an obturator or retropubic sling; no studies compared Burch urethropexy or pubovaginal slings to minislings. The majority of studies in this category used a TVT-Secur (Ethicon Gynecare, Cincinnati, OH) placed in either the "U" (similar to retropubic slings) or "H" (similar to obturator slings) configuration. While this product is no longer available in the United States, it was retained for this analysis because we thought that there was significant interest among physicians regarding this clinical question. By excluding studies with TVT-Secur (Ethicon Gynecare) from the analysis, a review and guideline on this question would not have been possible.

FIGURE 6
Metaanalysis for subjective cure: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Review of the evidence showed that both objective and subjective cure outcomes were improved with use of a full-length sling compared to a minisling.

Metaanalysis of objective cure outcomes significantly favored traditional full-length MUS, all of which happened to be an obturator sling (TVT-obturator), compared to minislings (OR, 4.16; 95% CI, 2.15–8.05) (Figure 8).

Results were similar for the metaanalysis of subjective cure outcomes (Figure 9). There were data included for both obturator and retropubic traditional MUS. Traditional MUS were found to be superior to minislings (OR, 2.65; 95% CI, 1.36–5.17).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies.

With respect to a comparison of AEs, the route (retropubic vs obturator) of the traditional full-length MUS is an important consideration (Table 3). For example, minislings have similar rates of postoperative OAB symptoms (5.4%) compared with obturator slings (5.3%), but somewhat lower rates than retropubic slings (6.9%). Exposure of the sling postoperatively is similar with either obturator slings (2.2%) or minislings (2.0%), but retropubic slings have somewhat lower rates than either (1.4%). Dyspareunia is rare with any type of sling, but is somewhat more common with a minisling (0.99%) than either a retropubic (<0.001%) or obturator (0.16%) sling. Minislings have the highest rate of urethral perforation (2.7% vs <1% for either retropubic or obturator), but the lowest rate of groin pain (0.62%) when compared to either route of MUS (1.5% for retropubic, 6.5% for obturator). Metaanalyses of the AE data failed to show a significant difference for OAB symptoms after surgery or return to the operating room for retention.

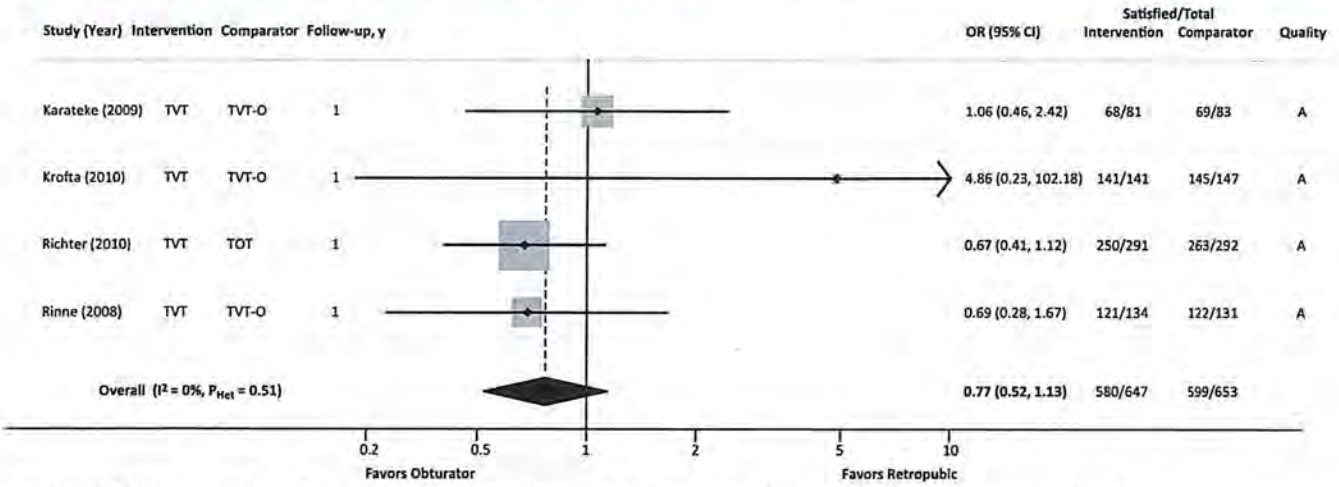
In summary, for women considering minislings or traditional full-length MUS, we recommend traditional full-length MUS to maximize cure rates (Table 4).

COMMENT

Surgical treatment of SUI has been well studied. MUS have become more common than pubovaginal sling procedures and Burch urethropexy for correction of SUI. In this systematic review we reviewed studies comparing MUS (retropubic, obturator, and minisling), pubovaginal slings, and Burch urethropexy for treatment of SUI in women. A large number of studies were available for review. In general, both the quality of study design and the inclusion of patient-centered outcomes have improved over time. We found low- to high-quality evidence permitting metaanalyses and development of clinical practice guidelines.

The best-studied comparison is for retropubic compared to obturator MUS, which included 21 separate studies. There appears to be little need to study

FIGURE 7
Metaanalysis for satisfaction: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

this further for straightforward SUI unless surgical products change significantly. We found few reliable data for subpopulations; patients who have urethral sphincter weakness or a history of surgical failure, for example, are often analyzed together with primary surgical candidates with normal urethral function. Definitions of these conditions were highly variable, which meant we were not able to perform reliable analyses of these data. As these are challenging populations to treat clinically, they should be better studied in future work. There is 1 trial that exclusively enrolled women with intrinsic sphincter deficiency, defined either by maximum urethral closure pressure of <20 cm H_2O or leak point pressures of <60 cm H_2O.[39,76,77] While urodynamic stress incontinence 6 months postoperatively was more common in patients undergoing an obturator sling, objective cure rates based on pad test at 6 months, perioperative information, overall definition of "success," and sexual function data showed no difference between slings.[39,76,77] For subjective cure rates, the obturator sling was favored only on analysis of Incontinence Impact Questionnaire-7 total score data at 3 years' follow-up, with other markers and time periods for subjective cure measures not different between groups.[39,76,77] Rate of reoperation for SUI at 3 years of follow-up favored the retropubic sling in this population (18.3% of women in obturator sling group vs 1.2% of the women in the retropubic sling group on intention-to-treat analysis, $P < .001$) with a significantly shorter time to reoperation in the obturator group as well.[39,76,77]

Comparing MUS vs Burch urethropexy, there is moderate-quality evidence that either procedure provides equivalent subjective and objective cure rates. The benefits of a minimally invasive approach may be offset by the inclusion of concomitant procedures. For example, if other intraabdominal procedures are planned, this may mitigate the perioperative differences and AEs associated with Burch surgery compared to a MUS.

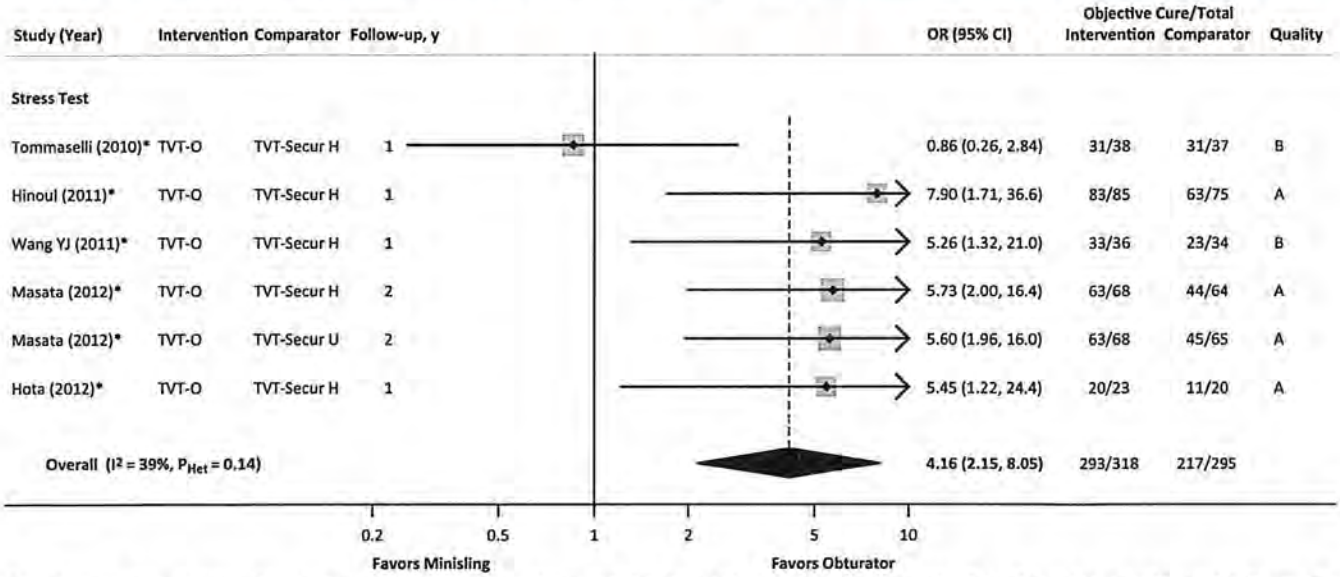
Only one study compared different types of pubovaginal slings to each other based on the type of sling material, and therefore we could not draw any conclusions on this question.[57]

We eliminated studies with <12 months' follow-up because of the robust body of literature on this topic (Table 1 presents length of follow-up for each study). Still, it is worthy to note that this is short-term from the perspective of a patient who desires lifelong cure. While challenging from an investigator standpoint, more studies with extended follow-up are needed.

One challenge in creation of clinical practice guidelines came when the importance of the various outcomes was weighed against each other. For example, should objective cure be more important overall than postsurgical sexual function? Many studies used composite success outcomes in an attempt to address this issue. The weight of these factors may also differ for surgeons and patients, and even between patients. For this reason, the clinical practice guideline statements provide detail to guide physician-patient counseling, which remains of paramount importance when planning surgery. Counseling also should address the impact of other concomitant procedures, such as hysterectomy and pelvic organ prolapse repair, in the decision-making process among the options for incontinence treatment.

Despite being the newest product on the market, the minislings had a large number of studies that met our inclusion criteria. Considering the interest in these slings, we thought it was merited to include TVT-Secur (Ethicon Gynecare)

FIGURE 8
Metaanalysis for objective cure: traditional midurethral sling (MUS) vs minisling



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

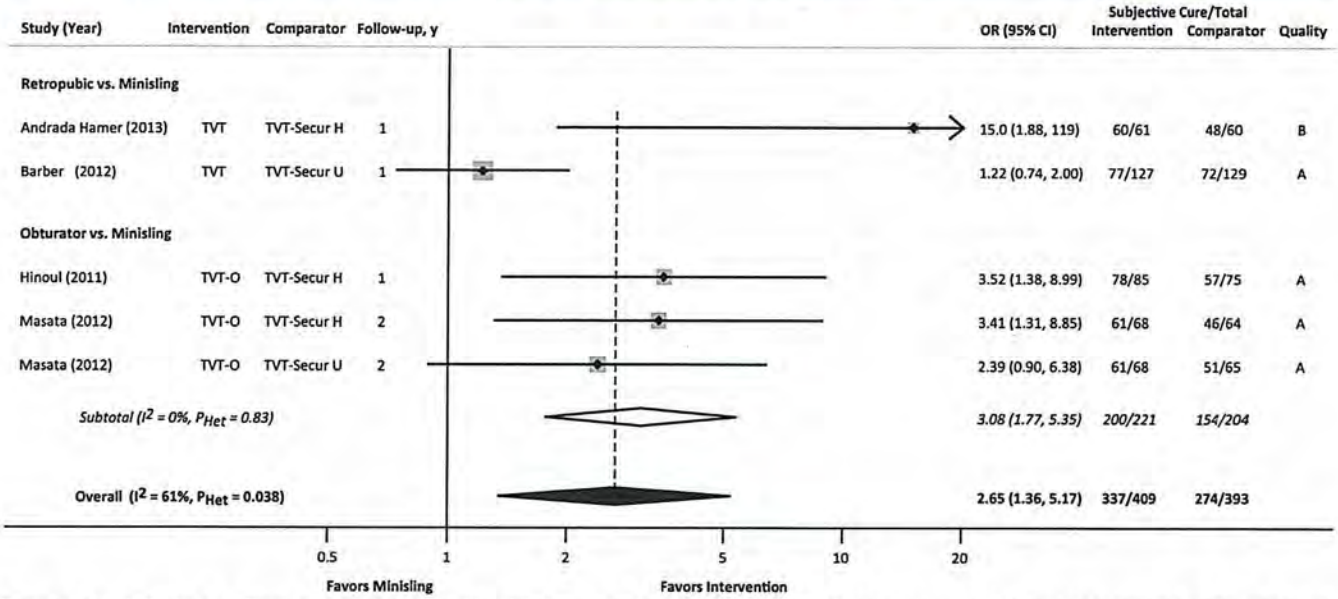
in our analysis although it has now been removed from the market. It should be noted that this is the most widely studied minisling, and the results of those studies and thus our review may not be generalizable to newer products. Further RCTs on these newer products are needed.

When choosing between surgical procedures, any surgeon must weigh the presumed benefits with the potential risks and AEs of these procedures. Balancing those against a specific patient's goals and desires is an important consideration for a diagnosis such as SUI in which treatment is elective based on degree of bother and quality-of-life impact. Additionally, surgeons should evaluate their own personal success and complication rates with the procedures and products they use, as these may differ from published rates. Whenever possible, physicians should counsel patients about the balance of both success rates and AEs for the various procedures discussed in this review. For example, some patients may tolerate some mild SUI to avoid any risk of obstructive OAB symptoms, while other patients would accept a high risk of needing to self-catheterize to avoid any SUI.

The strengths of this review include the large numbers of randomized clinical trials reviewed to provide data for the metaanalyses and clinical practice guidelines. Most of the randomized trials achieved their stated power and some studies reported long-term follow-up extending up to 5 years. Given the breadth of these data, we thought we could limit our review to studies with data at 12 months or longer, since patients and surgeons place higher value on long-term success rather than shorter-term rates. Our strict inclusion criteria, including the length of follow-up and the exclusion of meeting abstracts not submitted to the peer-review process, makes the included outcome data strong. There were also a large number of comparative cohort studies and observational studies to provide data on AEs. We were able to limit our collection to those studies with often >1000 patients to collect the most common problems rather than basing conclusions on rare, unusual events from smaller studies or case reports.

There are limitations to the study. Reporting of subpopulations of high interest to surgeons, including intrinsic sphincter deficiency and recurrent SUI, were variable and often not separated out from other patients in analyses, so we cannot draw conclusions about those populations. There was also high variability in reporting of numbers and types of complications in trials, making analyses of AE outcomes challenging. While many surgeons and patients are interested in information about postoperative symptoms such as urgency and de novo urgency, these symptoms were inconsistently reported, thus limiting their analysis. Additionally, data concerning need for retreatment were sparse and inconsistent, limiting our ability to draw any conclusions on this important question. Complications were assessed at different time intervals among different trials, and sometimes later trials reporting secondary analyses did not update longer-term AEs. The vast

FIGURE 9
Metaanalysis for subjective cure: traditional midurethral sling vs minisling



Forest plot subdivided by slings being compared with minisling. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

majority did not use a standard classification for complications such as the classification system of Dindo et al.[58] The length of follow-up for outcomes in most RCTs was up to 5 years but there was attrition as length of follow-up increased, which reduced the numbers of patients analyzed to determine long-term success rates for the slings or Burch urethropexy. Retropubic MUS, specifically TVT, is the best-studied procedure. There were few studies comparing different types of retropubic slings, obturator slings, or pubovaginal slings within those classifications, limiting our ability to comment on the best product/material.

In summary, this review supports the use of MUS for treatment of SUI compared to pubovaginal slings. The decision for retropubic vs obturator approaches to MUS may be based on the risks associated with each approach as no difference in effectiveness was found. The pubovaginal sling procedure is more effective than Burch urethropexy although, again, differences in surgical risks may guide the decision to utilize one approach over the other. Traditional MUS are significantly superior to minislings for cure outcomes. Overall, the evidence supporting use of MUS and pubovaginal slings is of high quality. These clinical practice guidelines provide an effective tool to assist in patient counseling and decision-making for the various surgical approaches to management of SUI. ■

REFERENCES

1. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 2010;362:2066-76.

2. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996;7:81-6.

3. Albo ME, Litman HJ, Richter HE, et al. Treatment success of retropubic and transobturator midurethral slings at 24 months. J Urol 2012;188:2281-7.

4. Wallace BC, Small K, Brodley C, Lau J, Trikalinos TA. Deploying an interactive machine learning system in an evidence-based practice center. In: Proceedings of the 2nd ACM SIGHIT International Health Informatics Symposium, Miami, Florida, 28–30 January. New York: Assoc Computing Machinery; 2012:819-24.

5. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions. J Clin Epidemiol 2010;63:513-23.

6. Trikalinos TA, Hoaglin DC, Schmid CH. Empirical and simulation-based comparison of univariate and multivariate meta-analysis for binary outcomes. Methods research report. (Prepared by the Tufts evidence-based practice center under contract no. 290-2007-10055-I.) AHRQ publication no. 13-EHC066-EF. Rockville, MD: Agency for Healthcare Research and Quality; March 2013.

7. Clopper C, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 1934;26:404-13.

8. Atkins D, Eccles M, Flottorp S, et al. GRADE Working Group. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches; the GRADE working group. BMC Health Serv Res 2004;4:38.

9. Bai SW, Sohn WH, Chung DL, Park JH, Kim SK. Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and

tension-free vaginal tape for stress urinary incontinence. Int J Gynaecol Obstet 2005;91:246-51.
10. Bandarian M, Ghanbari Z, Asgari A. Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence. J Obstet Gynaecol 2011;31:518-20.
11. Foote AJ, Maughan V, Carne C. Laparoscopic colposuspension versus vaginal suburethral slingplasty: a randomized prospective trial. Aust N Z J Obstet Gynaecol 2006;46:517-20.
12. Liapis A, Bakas P, Creatsas G. Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. Eur Urol 2002;41:469-73.
13. Paraiso MFR, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstet Gynecol 2004;104:1249-58.
14. Persson J, Teleman P, Etén-Bergquist C, Wolner-Hanssen P. Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. Acta Obstet Gynecol Scand 2002;81:1066-73.
15. Sivaslioglu AA, Caliskan E, Dolen I, Haberal A. A randomized comparison of transobturator tape and Burch colposuspension in the treatment of female stress urinary incontinence. Int Urogynecol J 2007;18:1015-9.
16. Tellez Martinez-Fornes M, Fernández Pérez C, Fouz López C, Fernández Lucas C, Borrego Hernando J. A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence. Actas Urol Esp 2009;33:1088-96.
17. Wang AC, Chen MC. Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial. Neurourol Urodyn 2003;22:185-90.
18. Ward K, Hilton P; United Kingdom and Ireland Tension-free Vaginal Tape Trial Group. Prospective multicenter randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ 2002;325:67.
19. Albo ME, Richter HE, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med 2007;356:2143-55.
20. Culligan PJ, Goldberg RP, Sand PK. A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:229-33.
21. Enzelsberger H, Helmer H, Schatten C. Comparison of Burch and Iyodura sling procedures for repair of unsuccessful incontinence surgery. Obstet Gynecol 1996;88:251-6.
22. Amaro JL, Yamamoto H, Kawano PR, Barros G, Gameiro MO, Agostinho AD. Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial. Int Braz J Urol 2009;35:60-7.
23. Guerrero KL, Emery SJ, Wareham K, Ismail S, Watkins A, Lucas MG. A randomized controlled trial comparing TVT, Pelvicol, and autologous fascial slings for the treatment of stress urinary incontinence in women. BJOG 2010;117:1493-503.
24. Sharifiaghdas F, Mortazavi N. Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up. Med Princ Pract 2008;17:209-14.
25. Tcherniakovsky M, Fernandes CE, Bezerra CA, Del Roy CA, Wroclawski ER. Comparative results of two techniques to treat stress urinary incontinence: synthetic transobturator and aponeurotic slings. Int Urogynecol J Pelvic Floor Dysfunct 2009;20:961-6.
26. Aniuliene R. Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence. Medicina (Kaunas) 2009;45:639-43.
27. Araco F, Gravante G, Sorge R, et al. TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:917-26.
28. Ballester M, Bui C, Frobert J, et al. Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicenter study comparing the retropubic and transobturator routes. World J Urol 2012;30:117-22.
29. Barber MD, Kleeman S, Karram MM, et al. Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2008;111:611-21.
30. Deffieux X, Daher N, Mansoor A, Debodinance P, Muhlstein J, Fernandez H. Transobturator TVT-O versus retropubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up. Int Urogynecol J 2010;21:1337-45.
31. El-Hefnawy AS, Wadie BS, El Mekresh M, Nabeeh A, Bazeed MA. TOT for treatment of stress urinary incontinence: how should we assess its equivalence with TVT? Int Urogynecol J 2010;21:947-53.
32. Freeman R, Holmes D, Hillard T, et al. What patients think: patient-reported outcomes of retropubic versus transobturator mid-urethral slings for urodynamic stress incontinence—a multicenter randomized controlled trial. Int Urogynecol J 2011;22:279-86.
33. Karateke A, Haliloglu B, Cam C, Sakalli M. Comparison of TVT and TVT-O in patients with stress urinary incontinence: short-term cure rates and factors influencing the outcome: a prospective randomized study. Aust N Z J Obstet Gynaecol 2009;49:99-105.
34. Krofta L, Feyereisl J, Otcenásek M, Velebil P, Kasíková E, Krcmár M. TVT and TVT-O for surgical treatment of primary stress urinary incontinence: prospective randomized trial. Int Urogynecol J 2010;21:141-8.
35. Liapis A, Bakas P, Giner M, Creatsas G. Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence. Gynecol Obstet Invest 2006;62:160-4.
36. Rinne K, Laurikainen E, Kivelä A, et al. A randomized trial comparing TVT with TVT-O: 12-month results. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1049-54.
37. Ross S, Robert M, Swaby C, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. Obstet Gynecol 2009;114:1287-94.
38. Scheiner DA, Betschart C, Wiederkehr S, Seifert B, Fink D, Perucchini D. Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings. Int Urogynecol J 2012;23:197-206.
39. Schierlitz L, Dwyer PL, Rosamilia A, et al. Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial. Obstet Gynecol 2008;112:1253-61.
40. Teo R, Moran P, Mayne C, Tincello D. Randomized trial of tension-free vaginal tape and tension-free vaginal tape-obturator for urodynamic stress incontinence in women. J Urol 2011;185:1350-5.
41. Wang F, Song Y, Huang H. Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China. Arch Gynecol Obstet 2010;281:279-86.
42. Wang W, Zhu L, Lang J. Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence. Int J Gynaecol Obstet 2009;104:113-6.
43. Wang YJ, Li FP, Wang Q, Yang S, Cai XG, Chen YH. Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 2011;22:1369-74.
44. Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomized trial. Eur Urol 2007;51:1376-84.
45. Andonian S, Chen T, St-Denis B, Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. Eur Urol 2005;47:537-41.
46. Tseng LH, Wang AC, Lin YH, Li SJ, Ko YJ. Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:230-5.
47. Abdel-Fattah M, Ramsay I, Pringle S, et al. Randomized prospective single-blinded study

comparing "inside-out" versus "outside-in" transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study. BJOG 2010;117:870-8.
48. Andrada Hamer M, Larsson PG, Teleman P, Bergqvist CE, Persson J. One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogynecol J 2013;24:223-9.
49. Barber MD, Weidner AC, Sokol AI, et al. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2012;119:328-37.
50. Hinoul P, Vervest HA, den Boon J. A randomized, controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence. J Urol 2011;185:1356-62.
51. Hota LS, Hanaway K, Hacker MR, et al. TVT-Secur (Hammock) versus TVT-obturator: a randomized trial of suburethral sling operative procedures. Female Pelvic Med Reconstr Surg 2012;18:41-5.
52. Kim JJ, Lee YS, Lee KS. Randomized comparative study of the U- and H-type approaches of the TVT-Secur procedure for the treatment of female stress urinary incontinence: one-year follow-up. Korean J Urol 2010;51:250-6.
53. Lee KS, Lee YS, Seo JT, et al. A prospective multicenter randomized comparative study between the U- and H-type methods of the TVT SECUR procedure for the treatment of female stress urinary incontinence: 1-year follow-up. Eur Urol 2010;57:973-9.
54. Masata J, Svabik K, Zvara K, et al. Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women—2-year follow-up. Int Urogynecol J 2012;23:1403-12.
55. Oliveira R, Botelho F, Silva P, et al. Exploratory study assessing efficacy and complications of TVT-O, TVT-Secur, and Mini-Arc: results at 12-month follow-up. Eur Urol 2011;59:940-4.
56. Tommaselli GA, Di Carlo C, Gargano V, Formisano C, Scala M, Nappi C. Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 2010;21:1211-7.
57. Barbalias G, Liatsikos E, Barbalias D. Use of slings made of indigenous and allogenic material (Goretex) in type III urinary incontinence and comparison between them. Eur Urol 1997;31:394-400.
58. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205-13.
59. Jelovsek JE, Barber MD, Karram MM, Walters MD, Paraiso MF. Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow-up. BJOG 2008;115:219-25.
60. Ward KL, Hilton P; UK and Ireland TVT Trial Group. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol 2004;190:324-31.
61. Ward KL, Hilton PUK and Ireland TVT Trial Group. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008;115:226-33.
62. Tennstedt S. Urinary Incontinence Treatment Network. Design of the stress incontinence surgical treatment efficacy trial (SISTEr). Urology 2005;66:1213-7.
63. Tennstedt SL, Litman HJ, Zimmern P, et al. Urinary Incontinence Treatment Network. Quality of life after surgery for stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1631-8.
64. Chai TC, Albo ME, Richter HE, et al. Complications in women undergoing Burch colposuspension versus autologous rectus fascial sling for stress urinary incontinence. J Urol 2009;181:2192-7.
65. Kraus SR, Lemack GE, Richter HE, et al. Changes in urodynamic measures two years after Burch colposuspension or autologous sling surgery. Urology 2011;78:1263-8.
66. Brubaker L, Richter HE, Norton PA, et al. 5-year continence rates, satisfaction and adverse events of Burch urethropexy and fascial sling surgery for urinary incontinence. J Urol 2012;187:1324-30.
67. Sand PK, Winkler H, Blackhurst DW, Culligan PJ. A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra. Am J Obstet Gynecol 2000;182:30-4.
68. Daraï E, Frobert J, Grisard-Anaf M, et al. Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicenter study comparing the retropubic and transobturator routes. Eur Urol 2007;51:795-801.
69. David-Montefiore E, Frobert J, Grisard-Anaf M, et al. Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomized multicenter study comparing the retropubic and transobturator routes. Eur Urol 2006;49:133-8.
70. Barber MD, Kleeman S, Karram MM, et al. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. Am J Obstet Gynecol 2008;199:666.e1-7.
71. Albo ME. The trial of mid-urethral slings (TOMUS): design and methodology. J Appl Res 2008;8:1-13.
72. Brubaker L, Norton PA, Albo ME, et al. Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the trial of mid-urethral slings (TOMUS) study. Am J Obstet Gynecol 2011;205:498.e1-6.
73. Zyczynski HM, Rickey L, Dyer KY. Sexual activity and function in women more than 2 years after midurethral sling placement. Am J Obstet Gynecol 2012;207:421.e1-6.
74. Laurikainen E, Valpas A, Kivelä A, et al. Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. Obstet Gynecol 2007;109:4-11.
75. Palva K, Rinne K, Aukee P, et al. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. Int Urogynecol J 2010;21:1049-55.
76. Schierlitz L, Dwyer PL, Rosamilia A. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. Obstet Gynecol 2012;119:321-7.
77. De Souza A, Dwyer PL, Rosamilia A, et al. Sexual function following retropubic TVT and transobturator Monarc sling in women with intrinsic sphincter deficiency: a multicenter prospective study. Int Urogynecol J 2012;23:153-8.
78. Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomized trial. Eur Urol 2010;58:671-7.
79. Abdel-Fattah M, Ramsay I, Pringle S, Hardwick C, Ali H. Evaluation of transobturator tapes (E-TOT) study: randomized prospective single-blinded study comparing inside-out vs outside-in transobturator tapes in management of urodynamic stress incontinence; short term outcomes. Eur J Obstet Gynecol Reprod Biol 2010;149:106-11.
80. Abdel-Fattah M, Mostafa A, Familusi A, Ramsay I, N'dow J. Prospective randomized controlled trial of transobturator tapes in management of urodynamic stress incontinence in women: 3-year outcomes from the evaluation of transobturator tapes study. Eur Urol 2012;62:843-51.
81. Barry C, Lim YN, Muller R, et al. A multicenter, randomized clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:171-8.
82. Basu M, Duckett J. A randomized trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. BJOG 2010;117:730-5.
83. Bernasconi F, Napolitano V, Natale F, Leone V, Lijoi D, Cervigni M. TVT SECUR system: final results of a prospective, observational, multicentric study. Int Urogynecol J 2012;23:93-8.
84. But I, Faganelj M. Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:857-61.

85. Campeau L, Tu LM, Lemieux MC, et al. A multicenter, prospective, randomized clinical trial comparing tension-free vaginal tape surgery and no treatment for the management of stress urinary incontinence in elderly women. Neurourol Urodyn 2007;26:990-4.
86. Carey JM, Leach GE. Transvaginal surgery in the octogenarian using cadaveric fascia for pelvic prolapse and stress incontinence: minimal one-year results compared to younger patients. Urology 2004;63:665-70.
87. Cholhan HJ, Lotze PM. Urodynamic changes after tension-free sling procedures: Mycromesh-Plus vs TVT sling. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:217-25.
88. De Ridder D, Berkers J, Deprest J, et al. Single incision mini-sling versus a transobturator sling: a comparative study on MiniArc and Monarc slings. Int Urogynecol J 2010;21:773-8.
89. Dyrkorn OA, Kulseng-Hanssen S, Sandvik L. TVT compared with TVT-O and TOT: results from the Norwegian national incontinence registry. Int Urogynecol J 2010;21:1321-6.
90. Frederick RW, Carey JM, Leach GE. Osseous complications after transvaginal bone anchor fixation in female pelvic reconstructive surgery: report from single largest prospective series and literature review. Urology 2004;64:669-74.
91. Haverkorn RM, Williams BJ, Kubricht WS III, Gomelsky A. Is obesity a risk factor for failure and complications after surgery for incontinence and prolapse in women? J Urol 2011;185:987-92.
92. Kennelly MJ, Moore R, Nguyen JN, Lukban J, Siegel S. Miniarc single-incision sling for treatment of stress urinary incontinence: 2-year clinical outcomes. Int Urogynecol J 2012;23:1285-91.
93. Kennelly MJ, Moore R, Nguyen JN, Lukban JC, Siegel S. Prospective evaluation of a single incision sling for stress urinary incontinence. J Urol 2010;184:604-9.
94. Kölle D, Tamussino K, Hanzal E, et al. Bleeding complications with the tension-free vaginal tape operation. Am J Obstet Gynecol 2005;193:2045-9.
95. Kuo HC. Long-term surgical results of pubovaginal sling procedure using polypropylene mesh in the treatment of stress urinary incontinence. Urol Int 2005;74:147-52.
96. Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 2002;81:72-7.
97. Lee JK, Dwyer PL, Rosamilia A, Lim YN, Polyakov A, Stav K. Persistence of urgency and urge urinary incontinence in women with mixed urinary symptoms after midurethral slings: a multivariate analysis. BJOG 2011;118:798-805.
98. Meschia M, Barbacini P, Baccichet R, et al. Short-term outcomes with the Ajust system: a new single incision sling for the treatment of stress urinary incontinence. Int Urogynecol J 2011;22:177-82.
99. Neuman M. Perioperative complications and early follow-up with 100 TVT-Secur procedures. J Minim Invasive Gynecol 2008;15:480-4.
100. Neuman M, Sosnovski V, Kais M, Ophir E, Bornstein J. Transobturator vs single-incision suburethral mini-slings for treatment of female stress urinary incontinence: early postoperative pain and 3-year follow-up. J Minim Invasive Gynecol 2011;18:769-73.
101. Norris JP, Breslin DS, Staskin DR. Use of synthetic material in sling surgery: a minimally invasive approach. J Endourol 1996;10:227-30.
102. Oliveira R, Botelho F, Silva P, et al. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. BJU Int 2011;108:1616-21.
103. Oliveira R, Silva A, Pinto R, et al. Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. BJU Int 2009;104:225-8.
104. Pickens RB, Klein FA, Mobley JD III, White WM. Single incision mid-urethral sling for treatment of female stress urinary incontinence. Urology 2011;77:321-4.
105. Presthus JB, Van Drie D, Graham C. MiniArc single-incision sling in the office setting. J Minim Invasive Gynecol 2012;19:331-8.
106. Pushkar DY, Godunov BN, Gvozdev M, Kasyan GR. Complications of mid-urethral slings for treatment of stress urinary incontinence. Int J Gynaecol Obstet 2011;113:54-7.
107. Rapp DE, Nazemi TM, Kobashi KC, Govier FE. Transvaginal bone-anchored sling for the treatment of female stress urinary incontinence: effect of Valsalva leak point pressure and prior pelvic surgery on outcomes. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1211-5.
108. Rodrigues FR, Maroccolo Filho R, Maroccolo RR, Paiva LC, Diaz FA, Ribeiro EC. Pubovaginal sling with a low-cost polypropylene mesh. Int Braz J Urol 2007;33:690-4.
109. Simsiman AJ, Powell CR, Stratford RR, Menefee SA. Suburethral sling materials: best outcome with autologous tissue. Am J Obstet Gynecol 2005;193:2112-6.
110. Staskin DR, Choe JM, Breslin DS. The Gore-Tex sling procedure for female sphincteric incontinence: indications, technique, and results. World J Urol 1997;15:295-9.
111. Tincello DG, Botha T, Grier D, et al. The TVT worldwide observational registry for long-term data: safety and efficacy of suburethral sling insertion approaches for stress urinary incontinence in women. J Urol 2011;186:2310-5.
112. Paparella R, Marturano M, Pelino L. Prospective randomized trial comparing synthetic vs biological out-in transobturator tape: a mean 3-year follow-up study. Int Urogynecol J 2010;21:1327-36.
113. Basok EK, Yildirim A, Atsu N, Basaran A, Tokuc R. Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates. Urol Int 2008;80:46-51.
114. Porena M, Costantini E, Frea B, et al. Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicenter randomized trial. Eur Urol 2007;52:1481-90.
115. Howden NS, Zyczynski HM, Moalli PA, Sagan ER, Meyn LA, Weber AM. Comparison of autologous rectus fascia and cadaveric fascia in pubovaginal sling continence outcomes. Am J Obstet Gynecol 2006;194:1444-9.
116. Meschia M, Pifarotti P, Spennacchio M, Buonaguidi A, Gattei U, Somigliana E. A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. Am J Obstet Gynecol 2004;190:609-13.
117. Tamussino KF, Hanzal E, Kölle D, Ralph G, Riss PA; Austrian Urogynecology Working Group. Tension-free vaginal tape operation: results of the Austrian registry. Obstet Gynecol 2001;98:732-6.

APPENDIX

SUPPLEMENTARY TABLE 1
Evidence profile for midurethral sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Effect	Outcome importance
Objective cure	9	994	1A (0), 4B (-1), 2B (-2), 2C (-2)	0	0	0	Moderate	No difference	Critical
Subjective cure	8	712	1A (-1), 2B (-1), 2B (-2), 3C (-2)	0	0	0	Moderate	No difference	Critical
Perioperative outcomes	9	964	1A (0), 4B (-1), 1B (-2), 3C (-2)	0	0	0	High	Favors midurethral	Variable
Quality of life	3	465	3B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	1	344	1B (-1)	NA	0	-1	Low	No difference	High
Total	10 separate studies								

Quality of overall evidence: moderate. Balance of benefits and harms: comparing midurethral slings (retropubic or obturator routes) to Burch (open or laparoscopic), there were no differences in objective or subjective cure, quality of life and sexual function outcomes. Metaanalyses for subjective and objective cure also showed no significant differences. There were not enough studies to perform a metaanalysis of subjective cure outcomes. Perioperative outcomes favored midurethral slings but long-term adverse event outcomes were less common with the Burch procedure. Metaanalysis of the adverse event outcomes where possible did not show a difference.

NA, not applicable.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 2
Evidence profile for PV sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Effect	Outcome importance
Objective cure	4	855	1A (0), 1B (-2), 1B (-1), 1C (-2)	0	0	0	High	Favors sling	Critical
Subjective cure	2	747	1A (0)	NA	0	0	High	Favors sling	Critical
Perioperative outcomes	3	819	1A (0), 1B (-1), 1C (-2)	0	0	0	High	Favors Burch	Variable
Quality of life	1	655	1A (0)	NA	0	0	High	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	4 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing PVS using fascia or synthetic material to Burch (open or laparoscopic) for SUI treatment, objective and subjective cure outcomes favor PVS. There was no difference seen for quality of life outcomes and no data regarding sexual functioning. Short-term (perioperative) and long-term adverse event outcomes favor Burch although some adverse events are less common with sling procedures.

NA, not applicable; *PVS*, pubovaginal slings; *SUI*, stress urinary incontinence.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 3
Evidence profile for pubovaginal sling vs midurethral sling

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	3	233	1B (-1), 1B (-2), 1C(-2)	0	0	0	Low	No difference	Critical
Subjective cure	4	305	2B (-2), 1C (-2)	0	0	0	Very low	No difference	Critical
Perioperative outcomes	4	383	2B (-1), 2C (-2)	-1	0	0	Low	Favors midurethral	Variable
Quality of life	3	342	2B (-1), 1C (-2)	0	0	0	Low	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	5 separate studies								

Quality of overall evidence: low. Balance of benefits and harms: comparing PVS (fascia or synthetic material) to synthetic midurethral slings (only retropubic passage was studied), objective and subjective cure outcomes as well as quality of life and sexual function outcomes showed no differences. There were not enough studies available to perform a metaanalysis for objective cure outcomes, but a metaanalysis for subjective cure significantly favored midurethral slings. Both short-term (perioperative) and long-term adverse event data in general favored midurethral slings although metaanalysis did not show a difference for selected adverse-event outcomes.

NA, not applicable; *PVS*, pubovaginal slings.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 4

Evidence profile for retropubic vs obturator sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	19	3354	7A (0), 6B (-1), 4B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Subjective cure	18	3186	6A (0), 2A (-1), 4B (-1), 2B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Perioperative outcomes	21	3811	8A (0), 10B (-1), 3C (-2)	-1	0	0	High	Most outcomes show no difference but wide range. For OR time, 10 studies show a difference and 8 favor obturator>retropubic. One study demonstrated that obturator sling patients were in hospital less time. For pain, 3 studies show a difference, 1 favoring retropubic and 2 favoring obturator.	Variable
Quality of life	15	2837	8A (0), 7B (-1)	0	0	0	High	No difference	Critical
Sexual functioning	10	2004	4A (0), 1A (-1), 4B (-2), 1B (-1)	0	0	0	High	No difference	High
Total	21 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing retropubic to obturator midurethral slings, there was no difference seen for objective cure, subjective cure, quality of life or sexual functioning outcomes. Metaanalysis favored retropubic slings for objective and subjective cure, although neither was significant. Metaanalysis for satisfaction favored obturator slings, but again was not significant. Adverse event data was variable across outcomes. Metaanalysis showed postoperative overactive bladder symptoms were more common with retropubic slings, but rates of retention and return to OR for erosion were similar.

OR, operating room.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 5
Evidence profile for retropubic vs retropubic sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	146	2B (-1)	0	0	0	Moderate	No difference	Critical
Subjective cure	1	84	1B (-1)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	2	146	2B (-1)	0	0	0	Moderate	No difference	Moderate
Quality of life	0	0	NA	NA	NA	NA	NA	NA	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	2 separate studies	146							

Quality of overall evidence: low. Balance of benefits and harms: comparing TVT (retropubic *bottom-up*) to SPARC (AMS, Minnetonka, MN) (retropubic *top-down*) in a population undergoing both prolapse repairs and anti-incontinence procedures, it is uncertain whether TVT is preferable to SPARC. There were few studies to analyze. Similar objective cure, perioperative event, and long-term adverse event rates (moderate quality evidence) and subjective cure rates (low quality evidence) are observed for TVT and SPARC. Data are insufficient to compare differences in postoperative QoL or sexual function. Adverse events could not be compared.

NA, not applicable; *QoL*, quality of life; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 6
Evidence profile for obturator vs obturator sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Subjective cure	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	1	80	1B (-1)	NA	0	-1	NA	NA	Variable
Quality of life	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Sexual functioning	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	High
Total	2 studies								

Quality of overall evidence: low. Balance of benefits and harms: in 2 studies comparing routes of obturator sling passage (in-to-out vs out-to-in) for SUI, it is uncertain which route is preferable. Similar objective cure, subjective cure, quality of life and sexual functioning results were seen with low-quality evidence. Data are insufficient to compare short- or long-term adverse events.

NA, not applicable; *SUI*, stress urinary incontinence.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 7
Evidence profile for minisling vs other

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	15	1916	7A (0), 1B (-1), 4B (-2), 3C (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Subjective cure	9	1516	3A (0), 4A (-1), 1B (-1), 1B (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Perioperative outcomes	15	1916	7A (0), 5B (-1), 3C (-2)	-1	0	0	Moderate	For EBL, no difference in most studies. For catheter time favors TVT-O or no difference. For pain, favors minisling. Hospital time not different. OR time results mixed.	Variable
Quality of life	9	1467	7A (0), 2B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	3	708	1A (0), 2B (-1)	0	0	sparse	Moderate	No difference	High
Total	15 arms								

Quality of overall evidence: high. Balance of benefits and harms: Comparing traditional MUS (TVT or TVT-O) to the minislings (TVT-Secur U or H position, MiniArc), both objective and subjective cure outcomes strongly favored the traditional MUS, including on metaanalyses of both types of cure outcomes. No difference was seen for quality of life or sexual functioning outcomes. Adverse event outcomes were mixed and may depend on which MUS passage would be chosen as an alternative; metaanalysis of adverse-event data showed no difference. MiniArc; AMS, Minnetonka, MN; TVT-Secure; Ethicon Gynecare, Cincinnati, OH.

EBL, estimated blood loss; *MUS*, midurethral slings; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

UROGYNECOLOGY

Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study

Sara Abbott, MD; Cecile A. Unger, MD, MPH; Janelle M. Evans, MD; Karl Jallad, MD; Kevita Mishra, MD; Mickey M. Karram, MD; Cheryl B. Iglesia, MD; Charles R. Rardin, MD; Matthew D. Barber, MD, MHS

OBJECTIVE: The purpose of this study was to describe the evaluation and management of synthetic mesh-related complications after surgery for stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP).

STUDY DESIGN: We conducted a multicenter, retrospective analysis of women who attended 4 US tertiary referral centers for evaluation of mesh-related complications after surgery for SUI and/or POP from January 2006 to December 2010. Demographic, clinical, and surgical data were abstracted from the medical record, and complications were classified according to the Expanded Accordion Severity Classification.

RESULTS: Three hundred forty-seven patients sought management of synthetic mesh-related complications over the study period. Index surgeries were performed for the following indications: SUI (sling only), 49.9%; POP (transvaginal mesh [TVM] or sacrocolpopexy only), 25.6%; and SUI + POP (sling + TVM or sacrocolpopexy), 24.2%. Median time to evaluation was 5.8 months (range, 0–65.2). Thirty percent of the patients had dyspareunia; 42.7% of the patients had mesh erosion; and 34.6% of the patients had pelvic pain. Seventy-seven percent of the patients had a grade 3 or 4 (severe) complication. Patients with TVM or sacrocolpopexy were more likely to have mesh erosion and vaginal symptoms compared with sling only. The median number of treatments for mesh complications was 2 (range, 1–9); 60% of the women required ≥2 interventions. Initial treatment intervention was surgical for 49% of subjects. Of those treatments that initially were managed nonsurgically, 59.3% went on to surgical intervention.

CONCLUSION: Most of the women who seek management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention; a significant proportion require >1 surgical procedure. The pattern of complaints differs by index procedure.

Key words: mesh excision, mesh-related complication, sling, synthetic mesh

Cite this article as: Abbott S, Unger CA, Evans JM, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J Obstet Gynecol 2014;210:163.e1-8.

Approximately 11% of women in the United States will require surgical intervention for either pelvic organ prolapse (POP) or stress urinary incontinence (SUI) by age 80 years. Of these women, up to 29% will undergo repeat surgery for symptom recurrence.[1,2] In response to these high recurrence rates, the placement of synthetic mesh during repair is being used increasingly in hopes of achieving more durable improvement.[3] Current evidence suggests that, although the use of such mesh may reduce objective symptom recurrence when compared with native tissue repair only, complications appear to increase.[4-6] Common complications include intraoperative bladder perforation, mesh erosion, chronic pelvic pain, dyspareunia, infection, and fistula formation.[4-16]

How to best balance the potential benefit of improved outcomes with the well-demonstrated risk of repair-related complications remains unclear. The Food and Drug Administration has responded by first issuing a public health warning in October 2008, which was followed by a safety communication in July 2011.[17,18] These warnings highlight the need for a thorough informed consent process but leave the ultimate decision regarding the use of synthetic mesh between clinician and patient. The purpose of this study was to describe the evaluation and management of complications from synthetic mesh after surgery for SUI and POP that were evaluated at 4 US tertiary referral centers. Results were intended to help elucidate the nature of possible complications, the context/circumstances in which they are most likely to occur, and the additional treatment that is typically required for managing these complications.

From the Center for Urogynecology and Reconstructive Pelvic Surgery, Obstetrics, Gynecology and Women's Health Institute, Cleveland Clinic, Cleveland (Drs Abbott, Unger, and Barber), and Advanced Urogynecology and Pelvic Surgery, The Christ Hospital, Cincinnati (Drs Evans and Karram), OH; Department of Urogynecology, MedStar Washington Hospital Center, Washington, DC (Drs Jallad and Iglesia); and Department of Urogynecology, Women & Infants Hospital of Rhode Island, Providence, RI (Drs Mishra and Rardin).

Received Aug. 7, 2013; revised Sept. 23, 2013; accepted Oct. 10, 2013.

Supported by the Foundation for Female Health Awareness, The Christ Hospital, Cincinnati, OH.

The authors report no conflict of interest.

Presented at the 33rd Annual Scientific Meeting of the American Urogynecologic Society, Chicago, IL, Oct. 3-6, 2012.

Reprints: Matthew Barber, MD, MHS, Mail Code A81, 9500 Euclid Ave., Cleveland, OH 44195. barberm2@ccf.org.

TABLE 1
Current Procedural Terminology and *International Classification of Diseases*, 9th Revision, codes used to identify potential subjects

Type of code	Code and explanation
Current Procedural Terminology	57267 Insertion of mesh or other prosthesis for repair of pelvic floor defect
	57295 Revision or removal of prosthetic vaginal graft (vaginal approach)
	57296 Revision or removal of prosthetic vaginal graft (abdominal approach)
	57426 Revision or removal of prosthetic vaginal graft (laparoscopic approach)
	57287 Revision or removal of sling for stress incontinence
International Classification of Diseases, 9th Revision	619.0 Fistula involving female genital tract
	623.2 Vaginal stricture
	625.0 Dyspareunia
	625.5 Pelvic pain syndrome
	625.9 Pelvic pain unspecified
	719.45 Pain, joint, pelvic region
	729.6 Foreign body in soft tissue
	788.20 Retention of urine
	788.21 Incomplete bladder emptying
	936 Foreign body in intestine or colon
	938 Foreign body in alimentary tract

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014. (continued)

TABLE 1
Current Procedural Terminology and *International Classification of Diseases*, 9th Revision, codes used to identify potential subjects (continued)

Type of code	Code and explanation
	939.0 Foreign body in bladder or urethra
	939.2 Foreign body vulva or vagina
	939.9 Foreign body in genitourinary tract
	959.9 Foreign body
	996.30 Mechanical complication of genitourinary device implant and graft
	996.65 Infection and inflammatory reaction because of genitourinary device, implant, or graft
	996.76 Mesh erosion
	V58.32 Removal of suture

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

Materials and Methods

This was a multicenter, retrospective analysis of all women who attended 4 US tertiary referral centers for evaluation and/or management of a complication that resulted from synthetic mesh placed during surgery for SUI and/or POP. The 4 sites included Cleveland Clinic (Cleveland, OH), The Christ Hospital (Cincinnati, OH), MedStar Washington Hospital Center (Washington, DC), and Women & Infants Hospital of Rhode Island (Providence, RI). All sites obtained individual institutional review board approval.

All sites underwent training to follow standardized data abstraction procedures. To identify potential subjects, a search of the medical/billing records was performed with the use of a uniform set of Current Procedural Terminology and International Classification of Diseases, 9th Revision, codes (Table 1). To reduce irrelevant results, sites were allowed to limit their search to patients of only those practitioners (including both gynecologists and urologists) who were known to have managed vaginal mesh complications. The charts of all potential subjects were screened by site-specific study personnel to determine whether eligibility criteria were met. To qualify for inclusion in the study, the patient had to undergo the index surgery in which synthetic mesh was initially placed on or after Jan. 1, 2006. Selection of this date was intentional because it represents the introduction of vaginal mesh use for treatment of POP and thus allows for a fairer comparison of the proportion of complications that result from the mesh that was used for SUI vs POP. Qualifying index surgeries included the following procedures during which synthetic mesh was placed (cases of biologic mesh use were not considered): (1) midurethral slings, (2) transvaginal mesh, kit or non-kit (TVM), (3) sacrocolpopexies, and (4) any combinations of 1-3. It was not required for the index surgery to have been performed at the study site. Subjects were included if they came to the study site for evaluation and/or management of a mesh-related complication by December 31, 2012, regardless of the type of treatment (eg, inpatient vs outpatient, conservative vs invasive), if any, that had been received at each respective study site.

For all eligible subjects, the following information was collected: demographics, medical history, information about the index surgery, nature of the synthetic mesh complication, management of the synthetic mesh complication, and classification of the mesh complication. Demographic and medical history data included age, race, parity, height, weight, hormonal status, smoking status, and relevant comorbidities (chronic steroid use, diabetes mellitus, and connective tissue disorders). Index surgery data included the date of the index surgery, location (whether it occurred at the study site), indication (SUI, POP, or both), exact procedure, approach, type/brand of synthetic mesh

that was used, and location of synthetic mesh placement. In the event that a patient had multiple procedures with synthetic mesh during the same surgery or had temporally separated surgeries that involved the placement of synthetic mesh, selection of the designated "index surgery" was left to the discretion of the trained study personnel and his/her professional opinion of which procedure was most likely directly related to the resulting complication. All perioperative complications during the index procedure (including bladder injury, bowel injury, hemorrhage, abscess, or other) and any concomitant procedures were also recorded.

The date of first examination at the study site for evaluation/management of the mesh complication and all symptoms were recorded. All management interventions (including observation only, medications, physical therapy, in-office surgery, and/or operating room surgery that required anesthesia) were recorded in chronologic order. If surgery was required for treatment of the complication, details of that treatment surgery, including operating room time, estimated blood loss, and perioperative or postoperative complications that occurred within 6 weeks after surgery were obtained. Posttreatment pain scores at the first follow-up examination that occurred at least 4 weeks after the most invasive intervention and at the last available follow-up examination were also recorded. Finally, the available data were used to classify each patient according to the expanded Accordion classification of general surgical complications, which is a multilevel categorization system that grades postoperative complications by severity and extent of management that includes criteria such as noninvasive vs invasive procedures, organ system failure, anesthesia, and pharmacologic therapy.[19] It is the most widely used postoperative complication classification system across multiple fields of study and is therefore appropriate for the assessment of mesh-related complications.

Study data were collected centrally and managed with the use of REDCap electronic data capture tools that are hosted by the data-coordinating center, Cleveland Clinic. All data were analyzed with JMP software (version 9; SAS Institute Inc, Cary, NC.) All missing data points were treated as missing and not imputed. Many outcomes are descriptive and, accordingly, only appropriate summary statistics were reported. When data are compared across index surgery group types (eg, sling only, TVM with sling, TVM without sling, and sacrocolpopexy with or without sling) pairwise comparisons that always used "sling only" as the reference group were calculated with the χ^2 test (Fisher exact test, 2-tailed).

TABLE 2
Study subject demographics (n = 347)

Variable	Measure
Age at time of index surgery, y[a]	56.6 ± 12.7
Median (range)	56.4 (24.9–91.8)
Race, n (%)[b]	
Non-Hispanic white	226 (65.3)
African American	11 (3.2)
Hispanic	8 (2.3)
Asian	1 (0.3)
Other	7 (2)
Do not know/not recorded	93 (26.9)
Parity, n[c]	2.6 ± 1.24
Median (range)	2 (0–9)
≥1, %	97.9
Body mass index, kg/m^2[d]	28.4 ± 5.3
Median (range)	27.6 (19.3–43.5)
Hormone status, n (%)[b]	
Premenopausal	73 (21.1)
Postmenopausal, do not know hormone replacement status	96 (27.7)
Postmenopausal, not on hormone replacement	104 (30.1)
Postmenopausal, on hormone replacement	40 (11.6)
Do not know/not reported	33 (9.5)
Smoking status, n (%)[b]	
Never	212 (61.3)
Previous	73 (21.1)
Current	43 (12.4)
Do not know/not reported	18 (5.2)
Comorbidities, n (%)[e]	
Chronic steroid use	7 (2)
Diabetes mellitus	23 (6.6)
Connective tissue disease	0

[a] n = 319; [b] n = 346; [c] n = 331; [d] n = 293; [e] n = 347.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

RESULTS

A total of 693 potential subjects across the 4 tertiary referral centers were

TABLE 3
Complaints at evaluation by index surgery type (n = 347)

Complaint	Total, n (%)	Procedure, n (%)				
		Sling only (n = 173)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Transvaginal mesh with or without sling combined (n = 148)	Sacral colpopexy with or without sling (8/25 have sling)
Mesh erosion/ exposure/extrusion	148 (42.7)	52 (30.1)	46 (60.5)[a]	35 (48.6)[a]	81 (54.7)	14 (56)[a]
Pain						
Pelvic pain	120 (34.6)	44 (25.4)	29 (38.2)[a]	38 (52.8)[a]	67 (45.3)	9 (36)
Leg pain	9 (2.6)	2 (1.2)	1 (1.3)	5 (6.9)[a]	6 (4.1)	1 (4)
Back pain	9 (2.6)	2 (1.2)	1 (1.3)	6 (8.3)[a]	7 (4.7)	0
Groin pain	14 (4)	4 (2.3)	4 (5.3)	6 (8.3)	10 (6.8)	0
Any type of pain symptom	125 (36)	46 (26.6)	29 (38.2)	40 (55.6)[a]	69 (46.6)	10 (40)
Vaginal						
Dyspareunia	104 (30)	34 (19.7)	35 (46.1)[a]	31 (43.1)[a]	66 (44.6)[b]	4 (16)
Pain to male partner during vaginal intercourse	37 (10.7)	14 (8.1)[11]	13 (17.1)[11]	7 (9.7)	20 (13.5)	3 (12)
Vaginal constriction	15 (4.3)	1 (0.6)	7 (9.2)[a]	6 (8.3)[a]	13 (8.8)	1 (4)
Vaginal discharge	32 (9.2)	8 (4.6)	7 (9.2)	6 (8.3)	13 (8.8)[b]	10 (40)
Vaginal spotting	39 (11.2)	8 (4.6)	16 (21.1)[a]	11 (15.3)[a]	27 (18.2)	4 (16)[a]
Any type of vaginal symptom	160 (46.1)	47 (27.2)	47 (61.8)[a]	46 (63.9)[a]	93 (62.8)	19 (76)[a]
Recurrent symptoms						
Recurrent or de novo prolapse	49 (14.1)	7 (4)	18 (23.7)[a]	22 (30.6)[a]	40 (27.0)[b]	2 (8)
Recurrent or de novo incontinence	87 (25.1)	51 (29.5)	27 (35.5)	6 (8.3)[a]	33 (22.3)	3 (12)
Infection						
Localized/abscess	37 (10.7)	21 (12.1)	4 (5.3)	9 (12.5)	13 (8.8)	3 (12)
Systemic	0	0	0		0	0
Lower urinary tract						
Fistula	6 (1.7)	1 (0.6)	3 (3.9)	2 (2.8)	5 (3.4)	0
Urinary obstruction	66 (19)	56 (32.4)	7 (9.2)[a]	1 (1.4)[a]	8 (5.4)	2 (8)[a]
Voiding dysfunction	98 (28.2)	60 (34.7)	20 (26.3)	15 (20.8)[a]	35 (23.6)	2 (8)[a]
Painful voiding	20 (5.8)	13 (7.5)	3 (3.9)	3 (4.2)	6 (4.1)	0
New onset incontinence	25 (7.2)	3 (1.7)	1 (1.3)	17 (23.6)[a]	18 (12.2)	4 (16)[a]
Other	26 (7.5)	14 (8.1)	5 (6.6)	6 (8.3)	11 (7.4)	1 (4)
Any lower urinary tract symptom	171 (49.3)	96 (55.5)	33 (43.4)	33 (45.8)	66 (44.6)	8 (32)[a]

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Complaints at evaluation by index surgery type (n = 347) *(continued)*

Complaint	Total, n (%)	Procedure, n (%)				
		Sling only (n = 173)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Transvaginal mesh with or without sling combined (n = 148)	Sacral colpopexy with or without sling (8/25 have sling)
Lower gastrointestinal tract						
Fistula	0	0	0	0	0	0
Fecal incontinence	6 (1.7)	1 (0.6)	0	5 (6.9)[a]	5 (3.4)	0
Obstructive defecation/tenesmus	16 (4.6)	2 (1.2)	5 (6.6)[a]	8 (11.1)[a]	13 (8.8)	1 (4)
Painful defecation/ dyschezia	2 (0.6)	0	1 (1.3)	1 (1.4)	2 (1.4)	0
Other	1 (0.3)	0	1 (1.3)	0	1 (0.7)	0
Any lower gastrointestinal symptom	22 (6.3)	3 (1.7)	7 (9.2)[a]	11 (15.3)[a]	18 (12.2)	1 (4)
Nerve injury	5 (1.4)	1 (0.6)	2 (2.6)	0	2 (1.4)	2 (8)
Obturator	1 (0.3)	0	1 (1.3)	0	1 (0.7)	0
Pudendal	1 (0.3)	1 (0.6)	0	0	0	0
Sciatic	1 (0.3)	0	0	0	0	1 (4)
Do not know/ not reported	2 (0.6)	0	1 (1.3)	0	1 (0.7)	1 (4)
Other	0	0	0	0	0	0

[a] Statistically significant difference at $\alpha = .05$ with the use of the χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [b] Statistically significant difference at $\alpha = .05$ with the use of the χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with or without sling against sacral colpopexy.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

identified with the Current Procedural Terminology and International Classification of Diseases, 9th Revision, codes listed in Table 1. Ultimately, 347 subjects (50.1%) met the eligibility criteria. Baseline demographics of the study population are provided in Table 2. Most patients were postmenopausal, with a mean age of 56.6 ± 12.7 years at the time of the index surgery. The overwhelming majority of the women (97.9%) were multiparous. Only 12.4% of them were known current smokers at the time of their index surgery; 6.6% of them had diabetes mellitus, and 2% of them used chronic steroids for another medical condition.

During the index surgery, 49.9% of the women underwent a procedure for SUI only (ie, sling); 25.6% of the women underwent a procedure for POP only, and 24.2% of the women underwent a procedure for both SUI and POP. Of those who had a POP procedure that involved synthetic mesh, 85.5% procedures were TVM, and 13.9% procedures were sacrocolpopexies. Just over one-half of the study subjects (50.4%) who received evaluation/management of a complication underwent their index surgery at that same study site.

Median time from index surgery to first examination at a participating tertiary referral study site was 5.8 months (range, 0–65.2 months); 25.7% of the women were seen at another facility before being seen at 1 of these sites. The most common complaints were mesh erosion (42.7%), pelvic pain (34.6%), and dyspareunia (30%), although most women (70.3%) had with >1 distinct symptom or complaint (median, 2; range, 0–8). Patients who were seen after TVM or sacrocolpopexies were significantly more likely to have mesh erosion and vaginal symptoms, compared with those who received a sling only (Table 3). Patients with complications after TVM had a significantly higher occurrence of pelvic pain, dyspareunia, vaginal spotting, vaginal constriction, and obstructed defecation than those after sling alone (Table 3). Compared with TVM, patients with complications after sacrocolpopexies were significantly more likely to complain of vaginal discharge but less likely to complain of dyspareunia or recurrent POP (Table 3). Voiding dysfunction was most common in those women who received a sling only (Table 3).

Symptoms were also grouped by severity with the use of the expanded Accordion classification. Overall, 77% of the women had a grade 3 or 4, which is a "severe" complication, according to the Accordion classification (Table 4). Patients whose index surgery involved TVM were significantly more likely to have a grade 4 complication (return to operating room/general anesthesia) than those who received a sling only (Table 4).

The median number of interventions/ treatments for each woman with a

TABLE 4
Complaint severity at evaluation according to the Accordion Expanded Classification[20] by index surgery type (n = 347)

		Procedure, n (%)			
Grade	Total, n (%)	Sling only (n = 173)	TVM with sling (n = 76)	TVM without sling (n = 72)	Sacral colpopexy with or without sling (8/25 have sling)
1[a]	39 (11.2)	27 (15.6)	4 (5.3)[b]	7 (9.7)	1 (4)
2[c]	25 (7.2)	14 (8.1)	2 (2.6)	6 (8.3)	3 (12)
3[d]	52 (15)	37 (21.4)	8 (10.5)[b]	3 (4.2)[b]	4 (16)
4[e]	215 (62)	88 (50.9)	58 (76.3)[b]	51 (70.8)[b]	17 (68)
5[f]/6[g]	0	0	0	0	0
Cannot be classified	16 (4.6)	7 (4)	4 (5.3)	5 (6.9)	0

[a] Mild complication that requires only minor invasive procedures that can be done at the bedside; [b] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) comparing transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [c] Moderate complication that requires pharmacologic treatment with drugs other than those allowed for minor complications (antibiotics, blood transfusions, and total parenteral nutrition); [d] Severe complication that requires an endoscopic, interventional procedure or reoperation without general anesthesia; [e] Severe complication that requires management by an operation with general anesthesia; [f] Severe complication: organ system failure; [g] Death.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

complication was 2 (range, 1–9); 60% of the women required ≥2 interventions. The initial treatment intervention was surgical for 49% and nonsurgical for 51%. Of those who initially were treated nonsurgically, 59.3% went on to surgical intervention (3.8% in-office, 90.5% in the operating room, and 5.7% both in-office and operating room). Of the women who initially had an in-office trimming of mesh, 73.3% eventually went to the operating room. The median number of surgeries per patient during the study time period was 1 (range, 0–6); 20.7% of the women required >1 surgery, and 7.8% of the women required >2 surgeries. Compared with sling-only patients, a lower proportion of patients whose index surgery involved TVM with sling underwent medical treatment first. Of the patients who did receive medical treatment, a higher proportion of women with TVM underwent surgery at the study site, compared with sling-only patients (Table 5). For those patients who did undergo surgical intervention in the operating room for treatment of their complication, trimming of mesh/partial mesh excision (area of eroded mesh excised only) was the most common first surgical procedure that was performed (50.9%), whereas complete mesh excision (removal of the entire intravaginal portion of mesh to the lateral arms where they leave the pelvis) was the next most common first procedure (26.9%; Table 6). Complete mesh excision as the first operating room intervention was more common in those who had TVM alone, compared with those that had sling alone (Table 6).

COMMENT

The purpose of this study was to describe the evaluation and management of complications from synthetic mesh after surgery for SUI and POP at 4 US tertiary referral centers. Several significant trends were noted. First, approximately one-half of the women (49.3%) who sought treatment of a mesh-related complication at a tertiary referral center actually underwent their index procedure at a facility other than that tertiary referral center. This trend has been reported in other studies as well.[12] This raises the potential concern that physicians who perform these mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh-related complications with no awareness of the existing magnitude of the issue.

Second, several trends were identified that suggested that the synthetic mesh that is used in the application of slings for the treatment of SUI has a more predictable and less severe course of complications compared with the synthetic mesh that is used for the management of POP. For instance, those patients whose index surgery involved a sling only were significantly less likely to experience an Accordion classification severity grade 4, which is a complication that requires a return to the operating room with general anesthesia, than were those women whose index surgery involved the use of TVM. Furthermore, complications after TVM tend to be more severe, are more chronic in nature, and can be more difficult to treat. For instance, mesh erosion, pelvic pain, dyspareunia, vaginal constriction, vaginal spotting, and obstructive defecation were all significantly more common after an index surgery with TVM than 1 with sling only. Contrarily, urinary obstruction and voiding dysfunction were the only complications that were observed significantly more frequently in those women whose index surgery involved sling only, which suggests that these symptoms may be more related to the actual incontinence procedure rather than the use of mesh for treatment. Additionally, those women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical reintervention. Such findings are important because increased interest in this issue from the Food and Drug Administration potentially threatens the continued use of synthetic mesh in pelvic floor surgery.

Despite the distinction in complication severity between TVM and sling-only procedures, complications that are associated with mesh in general are very concerning. Most patients (60%) received 2 or more unique interventions; even then, there was no guarantee of symptom resolution. Perhaps more surprisingly, 79.3% of all subjects underwent at least 1 surgical intervention, whether in-office or in the operating room. Of those who required any

TABLE 5
Management by index surgery type (n = 347)

Variable	Total, n (%)	Procedure, n (%)			
		Sling only (n = 146)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Sacral colpopexy with or without sling (8/25 have sling)
Proportion of women who underwent ≥2 reintervention surgeries	72 (20.1)	34 (23.3)	23 (30.3)	13 (18.1)	2 (8)
Proportion of women who underwent medical treatment first	177 (51)	96 (55.5)	26 (34.2)[a]	36 (50)	18 (72)
Proportion of women who did not undergo any reintervention surgery at study site	72 (20.1)	42 (24.3)	8 (10.5)[a]	17 (23.6)	5 (20)

[a] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

surgery, nearly one-quarter of the women (26.2%) required >1 surgery. These results suggest that mesh-related complications that are observed at tertiary referral centers are regularly severe enough to require surgical reintervention. Prospective studies that observe patients from the time of evaluation with complication through their various treatment episodes with measurable outcomes of symptom resolution will be necessary to answer the question of how to best manage various synthetic mesh complications and validate whether the high surgical reintervention rate in this study was justified.

Limitations of this study include its retrospective nature and the biases that are inherent in such an approach. Additionally, the use of coding queries to identify study subjects poses a challenge because not all data are always captured when they should be. Perhaps most importantly, there is no denominator for the total number of patients who underwent an SUI or POP procedure with synthetic mesh. Thus, we can make no comments about the rate at which such complications occur. We can only observe that when they do occur, the nature of the complication is usually severe and often requires surgical intervention. Nonetheless, this information

TABLE 6
Details of first surgical procedure to manage mesh complications

Variable	Total, n (%)[a]	Procedure, n (%)			
		Sling only (n = 128)	Transvaginal mesh with sling (n = 67)	Transvaginal mesh without sling (n = 55)	Sacral colpopexy with or without sling (n = 20)
Trimming of mesh/ partial excision[b]	138 (50.9)	59 (46.1)	37 (55.2)	27 (49.1)	15 (75)[c]
Release of mesh arms[d]	49 (18.1)	19 (14.8)	16 (23.9)	13 (23.7)	1 (5)
Complete mesh excision[e]	73 (26.9)	27 (21.1)	19 (28.4)	24 (43.6)[c]	2 (10)
Recurrent prolapse treatment	63 (23.2)	9 (7)	24 (35.8)	26 (47.3)	4 (20)
Recurrent incontinence treatment	40 (14.8)	14 (10.9)	9 (13.4)	14 (25.5)[c]	3 (15)
Other surgery	56 (20.1)	28 (21.9)	12 (17.9)	12 (21.8)	4 (20)

[a] n = 271; 275 women had surgery, 4 of which were in-office only); [b] Area of eroded mesh only excised[15]; [c] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [d] Incision made in ≥1 of the lateral mesh arms to release tension; [e] Removal of the entire intravaginal portion of the mesh to the lateral arms where they leave the pelvis.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

is helpful in depicting worst-case scenario outcomes, which can be central to informed consent discussions and decision-making.

REFERENCES

1. Olsen A, Smith V, Bergstrom J, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-6.

2. Hendris SL, Clark A, Nygaard I, et al. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol 2002;186:1160-6.

3. Mistrangelo E, Mancuso S, Nadalini C, et al. Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: a review of the risk of vaginal erosion. J Minim Invasive Gynecol 2007;14:564-9.

4. Hiltunen R, Nieminen K, Takala T, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007;110(suppl):455-62.

5. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol 2008;111:891-8.

6. Diwadkar GB, Barber MD, Feiner B, et al. Complication and reoperation rates after apical vaginal prolapse surgical repair. Obstet Gynecol 2009;113:367-73.

7. Firoozi F, Ingber MS, Moore CK, et al. Purely transvaginal /perineal management of complications from commercial prolapse kits using a new prostheses/grafts complication classification system. J Urology 2012;187:1674-9.

8. Tijdnik MM, Vierhout ME, Heesakkers JP, et al. Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. Int Urogynecol J 2011;22:1395-404.

9. Nguyen JN, Jakus-Waldman SM, Walter AJ, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol 2012;119:539-46.

10. Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. BJOG 2008;115:1350-61.

11. Marqulies RU, Lewicky-Gaupp C, Fenner DE, et al. Complications requiring reoperations following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol 2008;199:678.e1-4.

12. Ridgeway B, Walters MD, Paraiso M, et al. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. Am J Obstet Gynecol 2008;199:703.e1-7.

13. Sung VW, Rogers RG, Schaffer JI, et al. Graft use in transvaginal pelvic organ prolapse repair: a systematic review. Obstet Gynecol 2008;112:1131-42.

14. Chen CC, Ridgeway B, Paraiso MF. Biologic grafts and synthetic meshes in pelvic reconstructive surgery. Clin Obstet Gynecol 2007;50:383-411.

15. Deffieux X, de Tayra R, Huel C, et al. Vaginal mesh erosion after transvaginal cystocele repair using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. Int Urogynecol J Pelvic Floor Dysfunct 2007;18:73-9.

16. Baessler K, Hewson AD, Tunn R, et al. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol 2005;106:713-6.

17. US Food and Drug Administration. FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence. October 20, 2008. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM061976. Accessed July 31, 2012.

18. US Food and Drug Administration. FDA safety communication: update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. July 13, 2011. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed July 31, 2012.

19. Barber MD. Surgical techniques for removing problematic mesh. Clin Obstet Gynecol 2013;56:289-302.

20. Strasberg SM, Linehan DC, Hawkins WG. The accordion severity grading system of surgical complications. Ann Surg 2009;250:177-86.

Int Urogynecol J (2009) 20:703–709
DOI 10.1007/s00192-009-0844-7

ORIGINAL ARTICLE

Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape

Jens Christian Prien-Larsen · Lars Hemmingsen

Received: 29 October 2008 / Accepted: 13 February 2009 / Published online: 10 March 2009

Abstract
Introduction and hypothesis We compared cure rates of tension-free vaginal tape (TVT) with intravaginal slingplasty (IVS) and evaluated changes in cure rates over time.
Methods One hundred three underwent TVT and 213 underwent IVS. Follow-ups were done at 3 months, 1 year, and 5 years.
Results The following results were found: objective cure for TVT 98–95–94% vs. IVS 86–86–80% ($p<0.03$); subjective cure for TVT 82–79–74% vs. IVS 79–81–71% (NS). In IVS, a significant decline in subjective cure took place. Vaginal erosions were found in 11.8% of women in the IVS group and none in the TVT group.
Conclusions TVT is an effective and stable treatment, whereas IVS has a significant inferior objective cure rate, and a significant decline in subjective cure rate occurred over time. A high rate of vaginal erosions was found in the IVS group. We cannot recommend the use of multifilament polypropylene tape (IVS) for surgical treatment of stress urinary incontinence.

Keywords Intravaginal slingplasty · IVS · Long-term outcome · Multifilament tape · Stress urinary incontinence · Vaginal erosion

J. C. Prien-Larsen (✉)
Department of Gynecology and Obstetrics,
Nykobing Falster Hospital,
Fjordvej 15,
4800 Nykobing Falster, Denmark
e-mail: jcpr@regionsjaelland.dk

L. Hemmingsen
Department of Clinical Quality Assessment,
Region Sjaelland Sygehus Syd,
4700 Naestved, Denmark

Abbreviations

TVT	tension-free vaginal tape
IVS	intravaginal slingplasty
SUI	stress urinary incontinence
NS	not significant
BMI	body mass index
VE	vaginal erosion
PVR	postvoid residual urine

Introduction

Retropubic tension-free mid-urethral tape operation for treatment of female stress urinary incontinence (SUI) has become an established and worldwide used technique; it is easy to perform with a high rate of success and low rate of complication. The two procedures, tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS), use synthetic polypropylene tapes, and the main difference between the two devices is the use of monofilament polypropylene tape in the TVT procedure and multifilament polypropylene tape in the IVS procedure. The monofilament tape is a type 1 macroporous graft with a pore size larger than 75 μm that allows admission of macrophages, blood vessels, and collagen fibers. The multifilament tape is a type 3 macroporous graft with microporous components between the filaments, which allows admission of bacteria but not macrophages and neutrophilic granulocytes, and thus frequently results in infection and sinus tract formation [1]. Only few long-term follow-up data on TVT and even less on IVS procedures are available, the trails are relatively small, and the outcomes seems to be inconsistent concerning the cure rates and the changes in cure rates over the years [2]. Previous studies, mostly casuistics, have suggested that the IVS procedure is associated with high

complication rates regarding vaginal erosions (VE) [3–4]. The aim of the present study is to compare the short- and long-term cure rates of TVT and IVS procedures, to describe the incidence and timing of complications in terms of VE, and to evaluate the changes in cure rates over time.

Materials and methods

In a one-center prospective observational cohort study, a total of 316 women with urodynamic stress incontinence were enrolled consecutively. From February 1998 to June 2001, 103 women underwent the TVT (Gynecare) procedure; hereafter, the technique was changed, and 213 underwent the IVS (Tyco) procedure. There were no significant differences between the IVS and the TVT group concerning patient demographics, bladder function, or urodynamic testing; only the length of follow-up for the TVT group was longer than the IVS group (Tables 1 and 4).

All patients underwent standardized preoperative evaluation: filling cystometry and pressure flow study in a sitting position, a 24-h pad test, and a 2-day bladder diary, postvoid residual urine (PVR) measured by a catheter, a cough stress test in supine position, and a short-term pad test in standing position (ten vigorous coughs and the amount of urine loss was quantified by measuring the weight gain); both provocative stress tests were performed with a bladder volume of 300 ml saline and the bladder was filled in conjunction with PVR measurement [5, 7]. Lastly, a free uroflowmetry at voided volume ≥ 150 ml was done. The voiding function was assessed by maximum flow rate (Q_{max}), corrected Q_{max} ($Q_{max}/\sqrt{\text{voided volume}}$), average flow rate ($Q_{ave}$), flow time, time to maximum flow, and voided volume. Urodynamic testing, terminology, and diagnostic criteria are in accordance with the recommendations of ICS and IUGA [6, 7].

All patients had anterior vaginal wall prolapse < stage 2 (pelvic organ prolapse quantification), and no concomitant prolapse surgery was done [8]. All postmenopausal women were treated at least 1 month before operation with estrogen, mainly local.

Surgery procedure

All patients were operated on under local anesthesia, and two experienced surgeons performed more than 90% of the operations. A full-thickness midline incision was done at the vaginal mucosa under the mid-urethra, and the polypropylene tape was placed suburethrally touching the urethra and then adjusted while the patient coughed vigorously at a bladder volume of 300 ml. Cystoscopy was performed after the tape was placed. The suburethrally incision was closed with absorbable stitches. The Foley catheter was removed at the end of the operation. All patients received prophylactic cefuroxim 1.5 g intravenously under surgery.

Follow-up

Three standardized follow-up visits were done at 3 months, 1 year, and 5 years after surgery. Every visit included PVR, a cough stress test in supine position, and a short-term pad test in standing position, both with a bladder volume of 300 ml and free uroflowmetry at voided volume ≥150 ml.

Definition of treatment outcome

To evaluate the effect of treatment, both subjective (patients' perception of the clinical improvement expressed by open interview) and objective criteria were considered.

Subjective cure was regarded if the reported incontinence episodes were ≤1 per week (a reduction in incontinence episodes >90%), and the patient was satisfied.

Subjective improvement was defined as a reduction in incontinence episodes ≥75%, and the patient was satisfied. All other outcomes were regarded as failures.

Objective cure was regarded if cough stress test and short-term pad test was negative (pad weight gain <1 g).

Vaginal erosion was defined as the exposure of the tape within the vagina at suture line after healing of the vaginal incision. All patients with this condition were classified as treatment failures.

Table 1 Demographic detail of 316 women undergoing TVT and IVS operations for SUI

	TVT-group (N=103)	IVS group (N=213)	p (Mann–Whitney)
Age (years)	58.8 (27–84)	58.1 (31–84)	NS
BMI (kg/m^2)	27.2 (18.8–41.0)	27.7 (17.7–40.8)	NS
Parity	2.3 (0–7)	2.4 (0–9)	NS
Previous Surgery			
Once	14.5% (15/103)	10.3% (22/213)	NS
Twice	3.8% (4/103)	2.8% (6/213)	NS

Mean values, range in brackets. A p<0.05 is statistically significant

NS not significant

Statistical analysis

Data was analyzed using the statistical package SPSS and Mann–Whitney test (non-paired) and Wilcoxon signed ranks test (paired) were used.

Probability values less than 0.05 were considered statistically significant.

Results

Follow-up

The median length of follow-up in the TVT group was 78 months (range, 47–104), and 78 women (76%) were seen and evaluated by the protocol. In the IVS group, the median follow-up period was 56 months (range, 36–79) and 161 women (76%) were seen and evaluated; 24% in both groups had died or were unable to participate mostly due to illnesses related to high age.

Objective cure rates

Objective cure rates were significantly better at all follow-ups in the TVT group compared to IVS; the cure rates in the IVS group decreased between visits 2 and 3, but the trend toward a lower cure was not significant (Table 2).

Subjective cure rates

Subjective cure rates were equal in TVT and IVS at all follow-ups. Changes over time in subjective cure rates occurred in both groups: not significant in the TVT group, whereas in the IVS group, the decrease was significant between visits 2 and 3 and was due to vaginal erosion associated with the IVS procedure (Table 3).

There was a considerable change in bladder function after surgery in terms of flow and residual urine. A halving of free Q_{max} took place in both TVT and IVS. Between visits 2 and 3, the PVR increased significantly in both procedures. All other changes in bladder function between visits 2 and 3 were not significant (Table 4).

Vaginal erosion

Under the 5-year period of observation, 11.8% patients (19/161) have demonstrated VE, and these women did not differ significantly in terms of age, BMI, previous surgery, and parity compared to the entire IVS cohort; only 5.2% (1/19) had diabetes. No urethral or bladder erosion was found nor was vesico-vaginal fistula; one had a urethral-vaginal fistula. No patients were found to have multiple erosions simultaneously. There was no presence of inflammatory tissue.

Symptoms of VE

Recurrent incontinence was the most frequent symptom reported in 63%, and vaginal bloodstained/purulent discharge was reported in 53%; both symptoms were present in 26% (Table 5). No patients developed fever, and no severe pelvic infection or retropubic abscess was found; all had sinus tract formation along the tape on one or both sides of the urethra of which four were connected to a suprapubic skin abscess/purulent sinus. Only 5% were asymptomatic. The tapes were sent for microbiological examination, and they all revealed a wide variety of aerobic and anaerobic bacteria reflecting the vaginal microorganisms.

Time to presentation

The time from surgery to diagnosis of VE was evenly distributed over the period of observation: Four cases were identified in the first year, two in the second, four in the third, three in the fourth, four in the fifth, and two in the sixth year (Fig. 1). Fifteen of 19 patients (79%) had "relevant" symptoms (e.g., recurrent incontinence or bloodstained/purulent discharge) and therefore were referred directly to our department, where the VE were observed immediately; whereas in four patients (21%), the diagnosis

Table 2 Objective outcomes in the TVT group compared with the IVS group during long-term follow-up

Outcome	Procedure	Visit 1 (3months)	Visit 2 (12months)	Visit 3 (60months)	p_{2-1}	p_{3-2}
					Wilcoxon	
Cure	TVT	98% (96/98)	95% (89/94)	94% (73/78)	NS	NS
	IVS	86% (180/210)	86% (132/154)	80% (128/161)	NS	NS
	$p_{TVT-IVS}$ (Mann–Whitney)	0.0005	0.03	0.005		

Number of patients in brackets. A $p<0.05$ is statistically significant

NS not significant; p_{2-1} and p_{3-2} probability value for the difference in cure between visits 1 and 2 and visits 2 and 3, respectively; $p_{TVT-IVS}$ probability value for the difference in cure between TVT and IVS groups

Table 3 Subjective outcomes in the TVT group compared with the IVS group during long-term follow-up

Outcome	Procedure	Visit 1 (3months)	Visit 2 (12months)	Visit 3 (60months)	p_{1-2}	p_{2-3}
					Wilcoxon	
Cure	TVT	82% (83/101)	79% (74/94)	74% (57/77)	NS	NS
	IVS	79% (166/210)	81% (129/159)	71% (114/161)	NS	0.04
	$p_{TVT-IVS}$ (Mann–Whitney)	NS	NS	NS		
Improved	TVT	9% (9/109)	18% (17/94)	18% (14/77)	NS	NS
	IVS	15% (32/210)	13% (21/159)	14% (23/161)	NS	NS
	$p_{TVT-IVS}$ (Mann–Whitney)	NS	NS	NS		

A $p<0.05$ is statistically significant

NS not significant; p_{2-1} and p_{3-2} probability value for the difference in cure between visits 1 and 2 and visits 2 and 3, respectively; $p_{TVT-IVS}$ probability value for the difference in cure between TVT and IVS groups

was delayed because the patients were referred to non-gynecological departments due to less typical symptoms such as abscess and fistula after inguinal herniotomy or hematuria. In these four patients, the diagnosis was delayed half a year to 2 years.

Treatment of VE

Partial transvaginal tape removal—by excision or pulling—was required in all 19 patients and was done in the office without anesthesia in 13 patients. Due to a very small defect in six patients, the removal was done under general anesthesia. The defect in the vaginal mucosa was left open for spontaneous healing without antibiotics. Afterwards, four patients developed skin abscess few months later and had the remainder tape removed abdominally in general anesthesia. The first three patients with VE were initially treated conservatively with antibiotics and local estrogen and re-sutured, but the tapes were eventually removed due to persistent symptoms. Afterwards, the removal of the tapes in seven of the 19 patients (37%) needed no more treatment: Five were still continent and two improved

Table 4 Changes in bladder function in the TVT and the IVS group during long-term follow-up

	Preoperative	Visit 1 (3months)	Visit 2 (12monts)	Visit 3 (60months)	p_{pre-1}	p_{1-2}	p_{2-3}
					Wilcoxon test		
Free Q_{max} (ml/s)							
TVT	28.2	14.8	16.1	16.0	0.000	0.01	NS
IVS	27.7	17.3	17.6	18.0	0.000	NS	NS
$p_{TVT-IVS}$ (Mann–Whitney)	NS	0.037	NS	0.003			
Corrected Q_{max} (ml/s)							
TVT	1.66	0.88	0.95	0.96	0.000	0.05	NS
IVS	1.63	1.05	1.07	1.04	0.000	NS	NS
$p_{TVT-IVS}$ (Mann–Whitney)	NS	0.004	0.012	0.012			
Short-term pad test (g)							
TVT	70.5	0.0	0.3	1.2	0.000	NS	NS
IVS	59.9	3.1	1.9	3.1	0.000	NS	NS
$p_{TVT-IVS}$ (Mann–Whitney)	NS	0.000	NS	NS			
PVR (ml)							
TVT	7.1	30.3	34.6	46.0	0.000	NS	0.007
IVS	8.2	19.0	18.9	30.5	0.000	NS	0.000
$p_{TVT-IVS}$ (Mann–Whitney)	NS	NS	0.000	0.012			

A $p<0.05$ is statistically significant

NS not significant; *PVR* post-void residual; p_{pre-1} probability value for the difference between preoperative visit and visit 1; p_{1-2} probability value for the difference between visits 1 and 2; p_{2-3} the difference between visits 2 and 3; $p_{TVT-IVS}$ probability value for the difference between TVT and IVS groups

Table 5 Presenting symptoms in women with vaginal erosion

Symptoms	*n/N*	Percent
Asymptomatic	1/19	5
Recurrent incontinence	12/19	63
Bloodstained/purulent discharge	10/19	53
Suprapubic skin sinus/abscess	4/19	21
Pain in abdomen/urethra	2/19	11
Urethral-vaginal fistula	1/19	5
Vaginal bleeding	1/19	5
Diabetes Mellitus	1/19	5
Estrogen at moment of diagnosis	15/19	79

(Table 6). Three months after removal of the tape, the remaining 12 of the 19 (63%) patients got a new monofilament tape with success except in two, who presented with symptoms of VE 15 months after insertions; they were continent after removal of the remaining multifilament tape.

Discussion

In the present study, the outcomes of TVT were effective and stable in the long term, and despite a longer follow-up period, it was superior to IVS at all follow-ups in terms of objective cure rates, whereas no significant differences were found in subjective cure rates. Concerning changes in treatment outcomes during the long-term follow-up, none was seen in the TVT group, whereas in the IVS group, there was a significant decline in subjective cure rate between visits 2 and 3. Vaginal erosions were found in 11.8% of women in the IVS group compared to none in the TVT group, and the time to diagnosis was evenly distributed over the 56 months (range, 36–79) of observation.

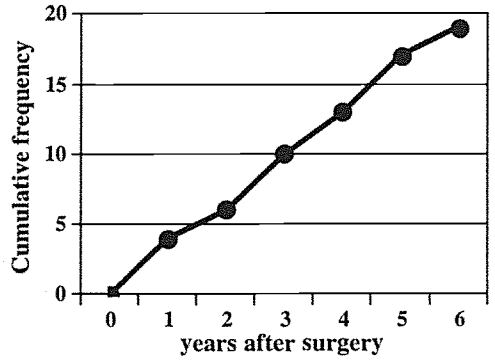


Fig. 1 Cumulative frequency of vaginal erosions during a period of 5 years after IVS operation. A total of 161 women were seen at 5 years follow-up, and vaginal erosion was found in 11.8% (19/161). The time from surgery to diagnosis was evenly distributed over the period of follow-up

Table 6 Status of continence after removal of the tape

	n/N	Percent
Cured	5/19	26
Improved	2/19	11
Failed	12/19	63

Many data on midurethral polypropylene tapes have been published, first and outmost on the TVT procedure and only few on IVS of which just three are randomized controlled trials comparing IVS to TVT. Interpretation and comparison of the results are not easy due to the following reasons: There is no consensus on the definition of SUI treatment outcome, the numbers of participants in the trials are often small, and the length of follow-up is short and variable [2]. Only very few IVS long-term follow-up studies are available [3, 4], and even fewer longitudinal IVS studies concerning the change in treatment outcome over 1 year has been conducted [15–16]. Concerning TVT procedure, only few publications have been published on changes in the voiding function over time [11–13].

Our result is consistent with the meta-analysis study by Novara et al. [2], who found that TVT is more efficacious than IVS in terms of objective cure rate, whereas the subjective cure rates were similar. Three randomized studies comparing TVT and IVS could not confirm our results. Rechberger et al. [17] found TVT and IVS equally efficacious in a short-term follow-up study, and like us, they found that the cure rate was slightly higher in TVT arm (88% vs. 80%, P=0.21). The study included only 50 patients in each arm and used mixed subjective and objective criteria to define cure. The median follow-up was only 13 1/2 months, and in this period, they did not find any vaginal erosions at all even though we found 26% of the vaginal erosions in the first year after surgery and the same did Lim et al. [19], who found 1.7% vaginal erosions during a very short-term observation of only 12 weeks. Otherwise, they found no significant difference between the groups with respect to subjective and objective outcomes. However, in the following 34 months, 13% of the patients were found to have suburethral sling erosions [24]. In the largest trial, Meschia et al. [18] reported data on 190 patients, randomized to 95 in each arm, using both objective and subjective criteria to define cure. Like us, they found a lower objective cure rate in the IVS group at 24 months follow-up, but the trend was not significant. Considering all the cases lost to follow-up as failures, the study showed significantly higher cure rate for the TVT group [2]. Concerning vaginal erosions in the IVS group, they found 9% compared to none in the TVT group [18].

Few other non-comparative IVS studies are available. Basok et al. [15] found a high mixed cure rate of 92% at

first visit and the mixed cure rate decreased to 45% after 12 months; opposite our result, the decrease was not caused by vaginal erosions because they found none during the 12 months of observation. In a retrospective study, Bafghi et al. [20] found vaginal erosions in 9.2% of the women during 12 months of observation. Until now, only two medium- to long-term follow-up IVS studies have been published; Sivaslioglu et al. [3] followed 98 patients and found a high mixed cure rate at 88% after 3 1/2 years, and they found 13.6% vaginal erosions. In a rather small (only 25 patients) 5-year follow-up study by Glavind et al. [4], a very high rate of complications in terms of vaginal erosions in 28% of the patients was found. While they found a very low cure rate, only 32% were continent 5 years after surgery.

Concerning the TVT group, our result is in accordance with the 11 years follow-up TVT study by Nilsson et al. [9], where both the subjective and objective cure rate was 81%; they neither found change over time nor vaginal erosions. Ankardal et al. [10] found the same result in a 5-year follow-up where the objective cure was 83%, but they found a decrease in subjective cure between 1 and 5 years (83% vs. 73%); no vaginal erosions were reported. In another 5-year follow-up study by Doo et al. [14], they found a significant falling cure rate between 1 and 5 years after surgery (90% vs. 77%). In a large multicenter trial with mixed urinary incontinence, Kulseng-Hansen et al. [21] found a low subjective cure rate at 60% after 38 months, and the objective cure was 64% in a subgroup of women with predominant stress incontinence. They also found a significant decrease in all cure parameters between 7 and 38 months after TVT (objective cure, 74% vs. 64%). No vaginal erosions were reported.

Concerning the reason for vaginal erosions associated with the use of multifilament polypropylene tape, Sivaslioglu et al. [3] concluded that the high erosion rates were due to the surgical technique rather than the property of the tape, and the same claim was proposed by Petros [23]. Chen et al [22] found an 8.3 times higher risk of vaginal erosions in patients with diabetes mellitus (DM). In our study, the basic surgical technique was as good as identical in both groups, and the main difference was the physical properties of the IVS and TVT tape. All patients were treated preoperatively with estrogen, and only one patient (5%) with erosion had DM. Our tapes were placed suburethrally touching the urethra as Sivaslioglu et al. [3] did; however, opposite the result of their study, we found 11.8% of vaginal erosions in the IVS group and none in the TVT group. Another cause of VE may be vaginal wound dehiscence in the immediate postoperative period due to bad closure technique, but this is unlikely since the standard closure technique was used in all cases—both TVT and IVS—and no VE were found among TVT patients.

We therefore believe that the cause of vaginal erosions was associated with the physical properties of the multifilament polypropylene tape in the IVS device and not by the technique of surgery or the presence of DM.

The first three patients with VE were initially treated conservatively with antibiotics and local estrogen and re-sutured, but the tapes were eventually removed due to persistent symptoms; afterwards, all vaginal erosions were actively managed with either partial or complete tape removal. Our results are consistent with the following studies: Meschia et al. [18] found no effect of antibiotics and topical vaginal estrogen in eight patients and neither did Bafghi et al. [25] in ten of 11 patients treated with antibiotics and surgical intervention. Consequently, we do not recommend conservative treatment of VE—caused by multifilament tape—but found partial removal of the tape necessary.

The present one-center, prospective cohort study has the disadvantage of not being randomized; however, there are several extenuating circumstances compensating for this drawback. To our knowledge, it is the largest IVS trial reporting data on 213 patients presented at the longest median follow-up of 56 months, using both objective and subjective criteria to define treatment outcome. Furthermore, the TVT group was reasonable large and the observation period long; besides, no differences were shown between the groups. Almost all surgery was performed by two experienced surgeons, the basic surgical technique was practically identical for the two devices, and the main difference was the physical properties of the tape.

As an implication of this study, we have stopped the use of multifilament polypropylene tape and have started paying attention to patients showing up with atypical symptoms after incontinent surgery, and a thorough gynecological examination should be undertaken. Furthermore, this study shows the importance of proper evaluation of long-term performance by means of large, prospective long-term follow-up studies after introduction of new operation techniques. More studies are needed concerning deterioration in cure rate over time.

Conclusion

TVT is an effective and stable treatment for SUI especially in the long term of 6 1/2 years. Even though the length of observation period in IVS was shorter and thus in favor of the IVS procedure, a significant inferior objective cure rate was demonstrated at all follow-ups, and deterioration occurred in subjective cure rate over time. Furthermore, we demonstrated an unacceptable high rate of vaginal erosions associated with the use of IVS.

Consequently, we must warn against the use of multifilament polypropylene tape in IVS for the surgical treatment of female SUI.

Conflicts of interest None.

References

1. Amid PK (1997) Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1:15–21
2. Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W (2007) Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol 52:663–679
3. Sivaslioglu AA, Unlubilgin E, Dölen I (2008) The multifilament polypropylene tape erosion trouble: tape structure vs. surgical technique. Int Urogynecol J 19:417–420
4. Glavind K, Larsen T (2008) Long-term follow-up of intravaginal slingplasty operation for urinary stress incontinence. Int Urogynecol J 19:1081–1083
5. Persson J, Bergqvist CE, Wølner-Hanssen P (2001) An ultra-short perineal pad-test for evaluation of female stress urinary incontinence treatment. Neurourol Urodyn 20:277–285
6. Abrams P, Cardozo L, Fall M (2002) The standardization of terminology of lower urinary tract function: report from the Standardization Sub-committee of the International Continence Society. Neurourol Urodyn 21:167–178
7. Ghoniem G, Stanford E, Kenton K (2008) Evaluation and outcome measures in the treatment of female urinary stress incontinence: international urogynecological association (IUGA) guidelines for research and clinical practice. Int Urogynecol J 19:5–33
8. Bump RC (1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 175:10–17
9. Nilsson CG, Palva K, Rezapour M, Falconer C (2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 19:1043–1047
10. Ankardal M, Heiwall B, Lausten-Thomsen N, Carnelid J, Milsom I (2006) Short and long-term results of the tension-free vaginal tape procedure in the treatment of female urinary incontinence. Acta Obstet Gynecol Scand 85:986–992
11. Dietz HP, Ellis G, Wilson PD, Herbison P (2004) Voiding function after tension-free vaginal tape: a longitudinal study. Aust N Z Obstet Gynecol 44:152–155
12. Sander P, Sørensen F, Lose G (2007) Does the tension-free vaginal tape procedure (TVT) affect the voiding function over time? Pressure-flow studies 1 year and 3 1/2 years after TVT. Neurourol Urodyn 26:995–997
13. Glavind K, Bjørk J, Nøhr M, Jaquet A, Glavind L (2006) A prospective study on whether a tension-free urethropexy procedure affects the residual urine and flow up to 4 years after the operation. Acta Obstet Gynecol 85:982–985
14. Doo CK, Hong B, Chung BJ, Kim JY, Jung HC, Lee KS, Choo MS (2006) Five-year outcomes of the tension-free vaginal tape procedures for treatment of female stress urinary incontinence. Eur Urol 50:333–338
15. Basok EK, Yildirim A, Atsu N, Gurbuz C, Tokuc R (2006) The surgical results of the pubovaginal sling procedure using intravaginal slingplasty (IVS) for stress urinary incontinence. Int Urol Nephrol 38:507–512
16. Kim JC, Chung BS, Choi JB, Lee JY, Lee KS Park WH (2007) A safety and quality of life analysis of intravaginal slingplasty in female stress incontinence: a prospective, open label, multicenter, and observational study. Int Urogynecol J 18:1331–1335
17. Rechberger T, Rzezniczuk K, Skorupski P, Adamiak A, Tomaszewski J, Baranowski W, Jakowicki JA (2003) A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J 14:432–436
18. Meschia M, Pifarotti P, Bernasconi F, Magatti F, Viganò R, Bertozzi R, Barbacini P (2006) Tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for stress urinary incontinence: a multicenter randomized trial. Am J Obstet Gynecol 195:1338–1342
19. Lim YN, Muller R, Corstiaans A, Dietz HP, Barry C, Rane A (2005) Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEEND trial. Aust N Z J Obstet Gynecol 45:52–59
20. Bafghi A, Valerio L, Benizri EI, Trastour C, Benizri EJ, Bongain A (2005) Comparison between monofilament and multifilament polypropylene tapes in urinary incontinence. Eur J Obstet Gynecol 122:232–236
21. Kulseng-Hanssen S, Husby H, Schiøtz HA (2008) Follow-up of TVT operations in 1113 women with mixed urinary incontinence at 7 and 38 months. Int Urogynecol J 19:391–396
22. Chen H-Y, Ho M, Hung Y-C, Huang L-C (2008) Analysis of risk factors associated with vaginal erosion after synthetic sling procedures for stress urinary incontinence. Int Urogynecol J 19:117–121
23. Petros P (2007) Monofilament and multifilament tape usage in incontinence surgery. Am J Obstet Gynecol 196(2):e12
24. Balakrishnan S, Lim YN, Barry C, Corstaiaans A, Kannan K, Rane A (2007) Sling distress: a subanalysis of the IVS tapes from the SUSPEND trial. Aust N Z J Obstet Gynecol 47:496–498
25. Bafghi A, Benizri EI, Trastour C, Benizri EJ, Michiels J-F, Bongain A (2005) Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling. BJOG 112:376–378

Long-term Results of the Tension-free Vaginal Tape Procedure in an Unselected Group: A 7-Year Follow-up Study

Andreas Reich, Frauke Kohorst, Rolf Kreienberg, and Felix Flock

OBJECTIVES To evaluate long-term effectiveness and late complications after treatment of female stress urinary incontinence with tension-free vaginal tape (TVT).

METHODS We performed a prospective observational study. Follow-up examinations included a standardized questionnaire, medical history, voiding diary, gynecologic examination with cough test, and introital ultrasound.

RESULTS One-hundred-eight women (68.8%) from the initial cohort of 157 patients and 79.6% of those alive and able to cooperate were assessed. The median follow-up time was 102 months (range 85-124). The objective cure rate was 89.8%. The subjective cure rate was 82.4%, 13% had improved, 2.8% regarded the continence situation as unchanged, and 1.8% had an impaired stress urinary incontinence. No late-onset adverse effects of the surgery were found. Urge incontinence was the main reason for dissatisfaction with the surgery (in 90% of discontent patients).

CONCLUSIONS Our data showed good results more than 7 years after TVT, demonstrating a high level of long-lasting efficacy for this minimally invasive incontinence procedure. UROLOGY 78: 774–777, 2011. © 2011 Elsevier Inc.

The tension-free vaginal tape (TVT, Gynecare, Ethicon, Inc., Somerville, NJ) was introduced in 1996[1] for the surgical management of female stress urinary incontinence (SUI). In the meantime, TVT has become the surgical treatment of choice for SUI in most cases despite the fact that there are only a few studies with long-term results with a follow-up of 7 years or longer.[2-5] In addition, some of these studies have been retrospective with the limitations this imposes on the interpretation of the results,[4,5] on data collected under the special conditions of a multicenter design,[2,4] or on creating a group comprised of only carefully selected primary cases.

Therefore, because of an increase in the life expectancy of women and an earlier point for surgical treatment of SUI, it is now more important than ever to collect long-term data after TVT procedure under practical conditions. This is also necessary because of the well-established data of Burch colposuspension.[6] Therefore, we prospectively investigated long-term results after TVT in a unicenter study with an unselected patient group (primary, recurrent, mixed, and low-pressure urethra cases and with concomitant pelvic organ prolapse surgery). The data from the follow-up of the same cohort after 40 months were published in 2006.[7]

MATERIAL AND METHODS

The retropubic TVT procedure was introduced in our department in August 1998 and was used to treat 157 consecutive women patients up to December 2001. One surgeon performed all the TVT operations. The TVT procedures were performed in accordance with the technique by Ulmsten et al.[1] Inclusion criteria were a history of SUI, a positive cough stress test, and a urodynamically proven SUI.

The follow-up in our study group was performed after 3 (range 1.5-10), after 40 (12-54), and after 102 (85-124) months. The follow-up evaluation included an interview, a standardized questionnaire (ICIQ, long form), a voiding diary, and a gynecologic examination with a cough test performed in the semilithotomy and standing positions with a comfortably filled bladder (200-250 mL). The bladder volume was estimated by introital ultrasound. Ultrasound imaging was used to obtain sagittal and transverse images of the largest cross sections of bladder visualized. The diameters were measured in 3 orthogonal directions: from the top to the bottom of the bladder (Y), at 90° to this diameter (Z) in the sagittal plane, and from left to right in the transverse plane (X). The residual volume was calculated using the formula for approximation of the ellipsoid ($X \times Y \times Z \times 0.81$). All patients gave informed consent to the study.

The basic characteristics of the 108 patients in the follow-up are shown in Table 1. When there was an additional associated procedure, TVT placement was performed at the end of surgery.

From the Department of Obstetrics and Gynecology, University of Ulm, Ulm, Germany; and Clinical Centre of Memmingen, Memmingen, Germany

Reprint requests: Andreas Reich, M.D., Department of Obstetrics and Gynecology, University of Ulm, Prittwitzstraße 43, 89075 Ulm, Germany. E-mail: andreas.reich@uniklinik-ulm.de

0090-4295/11/$36.00
doi:10.1016/j.urology.2011.06.009

Table 1. Demographic and clinical characteristics of the patients in the follow-up (n = 108)

Age at the time of surgery, year (range)	63 (44-86)
Stress incontinence grades (n)	
I°	15
II°	74
III°	19
Preexisting mixed incontinence, n (%)	27 (25%)
Low pressure urethra ≤20 cm H_2O (n)	44
Unknown	6
Body mass index (kg/m^2) (mean ± SD)	27.95 ± 4.33
Previous gynecologic surgery (n)	
Abdominal hysterectomy	32
Vaginal hysterectomy	40
Colporrhaphy	48
Abdominal sacrocolpopexy	3
Vaginal vault suspension	2
Previous incontinence surgery (n)	
Colpususpension	15
Needle suspension	1
Analgesia (n)	
Local	88
Spinal	19
General	1
Additional prolapse repair surgery (n)	
Anterior colporrhaphy	11
Posterior colporrhaphy	6
Colpocleisis	1

A patient was considered objectively continent if the result of the stress test in the lithotomy and standing positions was negative. The subjective cure rate of the TVT surgery for treatment of SUI was assessed using the standardized questionnaire. Classification of the surgical success as "SUI cured," "SUI improved," "SUI unchanged," or "SUI worse" in relation to the preoperative time was based on the patients' subjective opinion. Urge incontinence (UI) was defined as involuntary leakage of urine accompanied by urgency. General satisfaction with the operation (concerning incontinence) was assessed using a visual analogue scale (VAS), with 0% ("totally dissatisfied") up to 100% ("totally satisfied"). In addition, the general satisfaction with the result of the surgery was categorized by the patients as "very good," "good," "moderate," and "poor."

SPSS for Windows (SPSS, Inc., Chicago, IL) was used for data analysis.

RESULTS

Of the original 157 women included in the study, it was possible to evaluate 108 (68.8%) objectively and subjectively when they visited the clinic upon invitation. Thirty women died of natural causes and 2 women were not capable of cooperating. Only 17 women (10.8%) were lost to follow-up. After the primary TVT procedure only 2 women underwent further incontinence surgery (patient 1: TVT 4 months after the first TVT and after 10 years of injection therapy with Bulkamid; patient 2: colposuspension after 8 years and Bulkamid after 10 years). At follow-up these patients were assessed as failures. Table 1 shows the characteristics of the patients.

The median time of follow-up was 102 (range 85-124) months, an average of 8.5 years. In the study group we found an objective cure rate of 89.8% according to a negative stress test, whereas the subjective cure rate was 82.4%. Table 2 shows subjective cure rates during the follow-up. The mean general satisfaction of the operation on a VAS score was 87.5% after 102 (range, 85-124) months, 92% after 3 (range 1.5-10) months, and 90% after 40 (range 12-54) months. Satisfaction with the surgery was rated "very good" or "good" in 73.2% of the women after 102 (range 85-124) months. In contrast, this satisfaction was significantly higher with a mean of 3 (range .5-10) months (93.5%) and 40 (range 12-54) months (85.2%) after TVT (chi-square test, P <.001) (Table 3). The main reasons for dissatisfaction were UI or mixed incontinence. Figure 1 shows that 26 of 29 dissatisfied women (90%) were affected by UI in the long-term follow-up.

In the group of 81 patients without preoperative UI, 12 women (14.8%) developed a de novo UI 3 (range 1.5-10) months after surgery and 26 (32.1%) had UI after 102 (range 85-124) months. Of the patients with preexisting UI (n = 27), the rate of persisting UI was similar over the time (48.1% after 3 months and 59.3% after 102 months; chi-square test P = .08). At the time of follow-up investigation after 102 (range 85-124) months, 25 women had received an anticholinergic drug therapy.

In the study group we had 1 bladder perforation (0.9%) that was easily managed with a more lateral insertion of the trocar, 2 patients with perioperative bleeding with >100 mL (1.9%), and 1 case of a pulmonary embolism (0.9%) that occurred 3 weeks after surgery. During the long-term follow-up period, 2 patients developed urinary residual volumes of 130 mL and 180 mL without any subjective disorder and therefore did not need therapy. Because of pelvic organ prolapse, 4 patients required surgical therapy (2 posterior colporrhaphy, 1 vaginal hysterectomy with uterosacral ligament vault suspension, 1 abdominal sacrocolpopexy). Neither tape exposure nor cases of tape extrusion were detected. At the point of the follow-up investigation, 29 women were sexually active. No woman suffered under dyspareunia. No further late adverse effects, such as chronic pain or recurrent lower urinary tract infection, were found.

COMMENT

Here we present the results of a follow-up study with short-term, middle term, and long-term investigations in the same unselected group of patients with SUI. The time range of our assessments in the long-term follow-up is 39 months and is therefore a limitation concerning its explanatory powers. In our cohort we included patients with low-pressure urethra, previous incontinence surgery, mixed incontinence, and those with a need for additional prolapse surgery. Therefore, this study group represents a typical collective in a urogynecological unit. Nilsson et al[2] presented the longest follow-up after TVT to date in a prospective study design after 11.5 years. A limitation of this trial, however, was that exclusion criteria for

Table 2. Classification of the surgical success in relation to the preoperative time based on the patients' subjective estimation and the objective cure rate according to the clinical investigation with stress test (n = 108)

Cure Rate Subjectively	3 (1.5-10) Months	40 (12-54) Months	102 (85-124) Months
SUI cured	91.6%	83.3%	82.4%
SUI improved	7.4%	13.0%	13.0%
SUI unchanged	1.0%	2.8%	2.8%
SUI worse	0%	0.9%	1.8%
Cure rate objectively	91.6%	88.8%	89.8%

Table 3. Satisfaction with the TVT operation (concerning incontinence) based on the patients' subjective estimation (n = 108)

Satisfaction	3 (1.5-10) Months	40 (12-54) Months	102 (85-124) Months
Very good	80.5%	56.5%	55.6%
Good	13.0%	28.7%	17.6%
Moderate	6.5%	10.2%	19.4%
Worse	0%	4.6%	7.4%

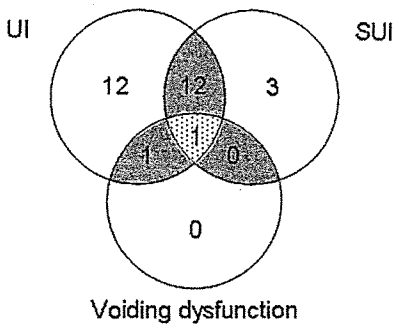


Figure 1. Reasons for dissatisfaction (surgical result categorized by 29 patients with "moderate" or "poor") 102 months after TVT procedure.

initial participation were low-pressure urethra, prior incontinence surgery, or the need for concomitant surgery.

The median age of our patients was 63 years and therefore considerably higher than in the other TVT long-term studies with a mean age between 50 and 55 years.[2,4,5] This explains the high mortality rate in our initial study group.

During the 8.5-year follow-up the objective cure rate was stable at about 90% in an aging cohort. The subjective cure rate declined during the follow-up by about 10% to a rate of 82.4%. Our results are in accordance with the efficacy rate reported in previous studies, when patient cure rates were studied 7-11.5 years after TVT procedures.[2-5]

Nilson et al[2] presented an objective cure rate of 90% and a subjective cure rate of 77% in 69 women after 11.5 years. In the study of Olsen et al,[5] 124 patients were retrospectively investigated with a follow-up of 11.5 years. The objective cure rate was 84% and the subjective cure rate was 77%. Liapsis et al[3] showed in a prospective 7-year follow-up an objective cure rate of 80% and a subjective cure rate of 78%. In another retrospective, multicenter study presented by Song et al,[4] the overall 7-year objective cure rate was 85% and the subjective cure rate was 69%. Another study done with mailed questionnaires focusing on subjective cure showed similar results after 83 months, with a cure rate of 80%.[8] These studies showed that the TVT procedure in the long term achieves an objective cure rate of SUI of about 80-90% and a subjective cure rate of about 70-80% with an additional improvement of SUI in about 10-20% of the patients.

In our study, 90% of dissatisfied patients had UI. Therefore, individual subjective satisfaction is associated with the prevalence of postoperative persistent or de novo UI. The rate of de novo UI in the literature is between 6% and 21%.[3-5] In our study group, we found a significantly higher rate of 32%. The high prevalence of UI in our study group may be explained in part by the higher age of our patients, because UI is associated with the aging process.[9,10] The influence of other possible reasons on the appearance of UI after TVT, such as mesh contraction, mild urethral obstruction, or urethral irritation, is still unclear.

Between 40% and 50% of the women after TVT implantation showed an improvement of UI.[9,11] The considerable influence of UI on satisfaction rates after TVT shows the need for more preoperative education and consistent postoperative therapy.

CONCLUSIONS

The TVT procedure leads to an ongoing high surgical success rate. The main reason for long-term dissatisfaction is UI, originating from a preexisting or a de novo disturbance. In contrast, approximately half of the patients with preexisting UI were cured in the long-term follow-up. We found no late adverse effects.

References

1. Ulmsten U, Henriksson L, Johnson P, et al. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 1996;7:81-86.
2. Nilson CG, Palva K, Rezapour M, et al. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. *Int Urogynecol J.* 2008;19:1043-1047.
3. Liapsis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. *Int Urogynecol J.* 2008; 19:1509-1512.

4. Song PH, Kim YD, Kim HT, et al. The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. *Br J Urol.* 2009;104:1113-1117.
5. Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. A retrospective follow-up 11.5 years post-operatively. *Int Urogynecol J.* 2010;21(6):679-683.
6. Lapitan MC, Cody DJ, Grant AM. Open retropubic colposuspension for urinary incontinence in women. *Cochrane Database Syst Rev.* 2003;1:CD002912.
7. Reich A, Kohorst F, Muche R, et al. Long-term results and influencing factors after tension-free vaginal tape (TVT). *Geburtsh Frauenheilk.* 2006;66:365-372.
8. Deffieux X, Donnadieu AC, Porcher R, et al. Long-term results of tension-free vaginal tape for female urinary incontinence: follow-up over 6 years. *J Urol.* 2005;14(6):521-526.
9. Chen YC, Chen GD, Hu SW, et al. Is the occurrence of storage and voiding dysfunction affected by menopausal transition or associated with the normal aging process? *Menopause.* 2003;10:203-208.
10. Irwin DE, Milsom I, Hunskaar S, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. *Eur Urol.* 2006;50(6):1306-1314.
11. Doo CK, Hong B, Chung BJ, et al. Five-year outcomes of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence. *Eur Urol.* 2006;50:333-338.

Int Urogynecol J (2008) 19:1509–1512
DOI 10.1007/s00192-008-0664-1

ORIGINAL ARTICLE

Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up

A. Liapis · P. Bakas · G. Creatsas

Received: 22 February 2008 / Accepted: 18 May 2008 / Published online: 10 June 2008

Abstract The objective of the study was to obtain a prospective assessment of the efficacy and the complications associated with the use of tension-free vaginal tape (TVT) for the management of urodynamic stress incontinence at 5- and 7-year follow-up. Sixty-five female patients with stage I cystocele or less who have been operated with TVT procedure for management of urodynamic stress incontinence have been included in the study. At 5-year follow-up, the objective cure rate was 83% and failure rate 9.4%. At 7-year follow-up, the objective cure rate was 80% and the failure rate 13.5%. De novo detrusor overactivity was seen in 9.4% and 11.4% of patients at 5- and 7-year follow-up, respectively. TVT operation is an effective and safe minimally invasive procedure for the management of urodynamic stress incontinence in women without significant cystocele in the long-term follow-up. The 10- and 20-year results are awaited.

Keywords Efficacy · Long term · Results · Stress incontinence · TVT · Urinary incontinence

Introduction

The tension-free vaginal tape (TVT) is a relatively new procedure that has been designed for the surgical management of stress urinary incontinence in women. It has been introduced since 1995 [1] and has achieved worldwide popularity since then. The short-term results of the procedure have been encouraging [2] and are comparable to the Burch colposuspension, which is considered the most successful operation for stress urinary incontinence in women available to date. In addition, it is characterized by less operative time, significantly less surgical complications and postoperative voiding dysfunction, less hospitalization time, and faster recovery [3, 4]. During the last few years, the long-term results of TVT procedure started appearing in the literature [5], but there are limited data yet. In this study, we present our experience in relation to long-term efficacy of TVT procedure for the management of stress urinary incontinence in women.

A. Liapis (✉) · P. Bakas · G. Creatsas
2nd Department of Obstetrics and Gynecology,
Aretaieio Hospital, University of Athens,
N. Paritsi 9A, N. Psichiko,
15451 Athens, Greece
e-mail: p_bakas@yahoo.com

Materials and methods

Seventy consecutive patients have been included in this study. It was estimated that, for a type I error-alpha 0.10 and a type II error-beta 0.10 (power of the study 90%) and an 82% success rate for TVT at 5 years follow-up, null hypothesis value to detect a success rate of 65% requires a sample size of at least 54 patients.

This prospective study took place in the 2nd Department of Obstetrics and Gynecology of the University of Athens. All patients were asked via telephone call to come for follow-up and underwent postoperative urodynamic assessment.

All patients had a full history taken and a complete gynecological examination performed at initial visit, and frequency–volume charts were completed for 2–4 days. Preoperative urodynamic investigations included filling and voiding cystometry, uroflow, and 1-h pad test. Stratification of severity of stress incontinence was based on the classification of pad weight gain suggested by the 5th Report of the International Continence Society, Bristol, 1987. Mild to moderate urine loss was observed in 31.4% of patients,

severe loss in 45.8%, and very severe loss in 22.8% of patients. Patient assessment at 5-year follow-up included gynecological examination, filling and voiding cystometry, uroflow, and 1-h pad test, and at 7 years follow-up included filling and voiding cystometry, uroflow, and a simple patient satisfaction questionnaire. Urodynamic stress incontinence diagnosis was based on the findings of urodynamic investigation. Diagnosis of detrusor overactivity was based on cystometric findings. All patients had USI with stage I prolapse or less of the anterior compartment according to the International Continence Society classification (ICSC). Patients with urodynamic findings of detrusor overactivity, previous operation in the genital tract or maximum urethral closure pressure of less than 20 cmH_2O, prolapse of the anterior compartment greater than stage I according to ICSC, or prolapse of the middle or posterior compartment requiring management were excluded from the study. All patients were operated on with epidural anesthesia. All patients signed an informed consent, and approval of the hospital ethical committee was obtained. The outcome of the operation was assessed both subjectively and objectively. Objective assessment was based on the findings of cough stress test by asking the patient to cough with the bladder filled with 400–450 ml of normal saline or filled up to maximum cystometric capacity. At 5-year follow-up, objective cure was considered as the absence of urine leaking during cough test in lithotomy or upright position and a pad test weight of <1 g, and improvement as the reduction of urine loss to less than 50% of urine loss they experienced before the operation. This was based on the findings of the 1-h pad test. Subjective cure was defined as no loss of urine with exercise, coughing, or weight lifting and improvement as a subjectively significant reduction of the leaking episodes, expressed by patients' satisfaction. At 7-year follow-up, objective cure was considered as the absence of urine leaking during cough test in lithotomy and upright position. In subjective cure, improvement and failure were assessed with the use of a simple questionnaire that patients answered during their examination ("Appendix"). Statistical analysis was performed for variables following normal distribution with the Student's *t* test for independent samples and for variables not following normal distribution with the Mann–Whitney test for independent samples. A $p<0.05$ was considered statistically significant. The software used for statistical analysis was Medcalc version 7.6.0.0.

Results

Of the 70 patients, five were lost at 5-year follow-up (three patients could not be located and two patients could not come for follow-up because they were living far away from the clinic). At 7-year follow-up, four additional patients were excluded because two of them had died from natural causes and two were living in a nursing home and could not attend for follow-up. The patients' characteristics are shown in Table 1. The objective cure rate was 83% at 5-years and 80% at 7-year follow-up. In the objective cure rate at 5- and 7-year follow-up, the patients having pure urge urinary incontinence have been included because they have been considered treated from their initial problem that was pure stress urinary incontinence. Total success rate, improvement, and failure rates at 5- and 7-year follow-up are presented in Tables 2 and 3. Cystocele grade II or higher was seen in 9.2% of patients at 5-year follow-up and in 12.5% at 7-year follow-up.

At 5-year follow-up, de novo detrusor overactivity was seen in 8% (5/65) of patients and urgency in 12.3% (8/65) of patients. Out of the five patients with detrusor overactivity, one patient had mixed incontinence and four patients had urge urinary incontinence (6.5%). Three out of five patients complained of dysuria, but they had postvoid residual volume (PVR) of urine of less than 100 ml and peak flow rates (PFRs) of 17.8, 13.4, and 13.8 ml/s, respectively.

At 7-year follow-up, de novo detrusor overactivity was seen in 11.4% (7/61) of patients and urgency in 19.6% (12/61). Out of seven patients with detrusor overactivity, two patients had mixed incontinence and five patients had urge urinary incontinence. Four out of seven patients complained of dysuria, and two of them had 80 and 60 ml PVR and 13.4 and 13.8 ml/s PFR, respectively, while the rest of the patients had PFR>15 ml/s and PVR<100 ml (Table 4). At 5-year follow-up, the median age of patients with bladder overactivity was 72 (range 55–78), and at 7-year follow-up the median age was 72 (range 57–80). At 7-year follow-up, overall subjective dysuria was 14.7% (9/61), but PVR was normal (median 5 ml, range 0–60 ml), and PFR median was 16.2 ml/s (range 13.4–24 ml/s). Recurrent lower urinary tract infection was seen in 3.2% of patients (2/61), but they had no complaints of dysuria or incontinence.

We had one case of TVT tape erosion developed at 29 months postoperatively which was treated by cutting the TVT tape edges which were projecting through the vaginal

Table 1 Patients' characteristics at 7-year follow-up

	Values (N=61)
Age (years)	58.1±10.4
Parity	2±1.1
BMI	26.8±2.3
Menopausal	70.4%

BMI Body mass index

Table 2 Outcome of surgery at 5-year follow-up

	Values	Percentage
Objective		
Cure	54/65	83
Improvement	5/65	7.6
Failure		
Mixed incontinence	1/65	1.5
USUI	5/65	7.6
Subjective		
Cured	55/65	84.6
Improved	3/65	4.6
Failed	7/65	10.7

USUI Urodynamic stress urinary incontinence

mucosa. The rest of the patients had no evidence of tape erosion at 7-year follow-up.

Discussion

The introduction of TVT procedure for the management of stress urinary incontinence in women was based on the integral theory. According to such theory, the female urethra is closed at the level of the midurethra and not at the bladder neck. Lack of support of the midurethra from the pubourethral ligaments and from the suburethral anterior vaginal wall and defective function and insertion of pubococcygeal muscles predisposes one to stress urinary incontinence [6, 7]. The purpose of the TVT procedure is to reinforce the midurethral support, and it uses a polypropylene mesh tape that is inserted beneath and around the midurethra [8].

The efficacy of TVT procedure in the short term has been reassuring and very encouraging, and this is supported by several papers [2, 9, 10].

In the present study, the objective cure rate is 83%, the objective improvement is 7.8%, and the failure rate is 9.2% at 5-year follow-up, while there is no significant difference from the results of subjective assessment. These results are similar with the 84.7% [11] and 94.5% [12] for pure stress urinary incontinence that has been reported, and it is comparable with the 78% for pure stress urinary incontinence that has been published [13]. At 7-year follow-up, the objective cure rate is 80%, the objective improvement is 6.5%, and the failure rate is 13%. These findings are comparable with the 81.3% cure rate that has been reported by Nilsson et al. [14]. De novo detrusor overactivity was seen in 11.4% of patients, while in the Nilsson et al. series de novo urge symptoms were 6.3%. The presence of detrusor overactivity was not associated with significant obstructive findings from the lower urinary tract and could at least be partly attributed to the aging of the patients.

These findings support that TVT procedure maintains its very good short-term efficacy in the long term, and it is very satisfactory for the patients and the physicians. We had no significant intraoperative complications, and we had no patients with voiding difficulties in the long term. There was only one case of erosion of vaginal mucosa by TVT tape, which was treated by cutting the edges of the TVT tape, and the patient remained continent. Its clinical presentation was as a sharp foreign body in the vagina, making sexual intercourse for her husband painful. These results are comparable with the Burch colposuspension [15], while TVT procedure is much less invasive, with fast recovery time and low rate of complications. However, Burch colposuspension presents a time-dependent decline in its efficacy, having a surgical success decline to 62% at more than 10-year follow-up [16]; at 14 or more years of follow-up, subjective cure rate could be reduced to 44% [17]. It has to be seen in the near future if the use of TVT tape as prosthetic material and the fibrotic tissue that is developed around it could maintain their function in the long term, preventing stress urinary incontinence. The incidence of de novo urgency at 5-year follow-up was 12.3%, which is in agreement with the results published by Doo et al. [13] wherein they report 11.5% incidence of de novo urgency and urge incontinence, higher than the 6% incidence of de novo urgency reported by Chene et al. [12].

Table 3 Outcome of surgery at 7-year follow-up

	Values	Percentage
Objective		
Cure	49/61	80
Improvement	4/61	6.5
Failure		
Mixed incontinence	2/61	3.2
USUI	6/61	9.8
Subjective		
Cured	48/61	78.7
Improved	5/61	8.1
Failed	8/61	13.1

USUI Urodynamic stress urinary incontinence

Table 4 Findings of filling and voiding cystometry at 5- and 7-year follow-up

	5 years (65 patients)	7 years (61 patients)	*p*
First desire (ml)	95.2±31.3	98.3±29.5	
Maximum cystometric capacity (ml)	363.2±60.7	362.4±57.7	NS
Maximal flow rate (ml/s)	16.7±1.8	16.6±2	NS
Postvoid residual (ml)	12.9±19.3	15.5±19.4	NS

NS No statistically significant difference

At 7-year follow-up, the incidence of de novo urgency was 19.6%, while other studies have reported an incidence of de novo urge symptoms at 6.3% [5]. The higher incidence of de novo urgency in the present study could be possibly attributed to the relatively smaller number of patients studied compared to that of other studies and to the aging of patients, which could contribute to a higher incidence of de novo urgency.

TVT procedure maintains a high efficacy at 5- and 7-year follow-up, which is comparable with the Burch colposuspension, but its efficacy at 10- and 20-year follow-up remains to be known. TVT procedure for the management of urodynamic stress incontinence appears to be a cost-effective technique at 5- and 7-year follow-up.

Conflicts of interest None.

Appendix

1. Do you feel cured from your stress urinary incontinence after the operation you had?
   YES NO
2. Do you think that your incontinence has been improved after the operation you had?
   YES NO
3. Do you think that you are about the same or worse after your operation for the management of your stress urinary incontinence
   About the same YES NO
   Worse YES NO

References

1. Ulmsten U, Petros P (1995) Intravaginal sling-plasty (IVS). An ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 29:75–82
2. Ulmsten U, Johnson P, Rezapour M (1999) A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br J Obstet Gynecol 106:345–350
3. Ward K, Hilton P (2002) Prospective multicentre randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress urinary incontinence. Br Med J 325:67–73
4. Liapis A, Bakas P, Creatsas G (2002) Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. Eur Urol 41:469–473
5. Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U (2001) Long term results of the tension free vaginal tape procedure for surgical treatment of female stress urinary incontinence. Int Urocynecol J 56(Suppl 2):S5–S8
6. Petros P, Ulmsten U (1990) An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand 69(Suppl 153):7–31
7. Petros P, Ulmsten U (1993) An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol 153:1–93
8. Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 7:81–86
9. Lo Ts, Chang TC, Chao As, Chou HH, Tseng LH, Liang CC (2003) Tension-free vaginal tape procedure on genuine stress incontinent women with coexisting genital prolapse. Acta Obstet Gynecol Scand 82:1049–1053
10. Karram MM, Segal JL, Vassallo BJ, Kleeman SD (2003) Complications and untoward effects of the tension free vaginal tape procedure. Obstet Gynecol 101:929–932
11. Liapis A, Bakas P, Creatsas G (2001) Management of stress urinary incontinence in women with the use of tension-free vaginal tape. Eur Urol 40(5):548–51
12. Chene G, Amblard J, Tardieu AS, Escalona JR, Viallon A, Fatton B, Jacquetin B (2007) Long term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. Eur J Obstet Gynecol RB 134:87–94
13. Doo CK, Hong B, Chung BJ, Kim JY, Jung HC, Lee KS, Choo MS (2006) Five year outcomes of the tension free vaginal tape procedure for treatment of female stress urinary incontinence. Eur Urol 50:333–338
14. Nilsson CG, Falconer C, Rezapour M (2004) Seven year follow up of the tension-free vaginal tape procedure for treatment of urinary incontinence. Obstet Gynecol 104:1259–1262
15. Jarvis GJ (1994) Surgery for genuine stress incontinence. Br J Obstet Gynecol 101:371–374
16. El-Toukhy T, Mahadevan S, Davies AE (2000) Burch colposuspension: a 10 to 20 years follow up. J Obstet Gynecol 20:178–179
17. Kjohede P (2005) Long term efficacy of Burch colposuspension: a 14 years follow up. Acta Obstet Gynecol Scand 84:767–772